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Clinical Efficacy of An Ayurvedic Formulation in the Management of *Vyanabala Vaishamy* w.s.r to Essential Hypertension

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ABSTRACT

Background: Hypertension is an important problem in the scenario of public health, owing to its more prevalence. Nearly 7.1 million lives are lost every year due to poor control of Hypertension. Hypertension is also known as “**Silent Killer**” of mankind because most sufferers (85%) are asymptomatic and as per available reports, in more than 95% cases of Hypertension, underlying causes are not found. The present study was carried out with an objective to find an alternative, reliable, safe and cost effective treatment for Hypertension and to study the etiopathogenesis of Hypertension in terms of *Ayurveda*.

Study design: The study was “Single Blind Study” conducted on 60 patients of **Essential Hypertension** of either sex. Patients were randomly recruited to two Groups (30 each). In Group A, patients were subjected through an *Ayurvedic* formulation prepared in the form of *Vati* with ingredients as *Jatamansi*, *Arjuna*, *Gokshura*, *Mandukparni*, *Sarpagandha* and *Tagara*. In Group B patient were subjected through Amlodipine (5mg).

Results: We can conclude that the overall effect of Group A (*Ayurvedic* formulation) was better in relieving the symptoms of Hypertension than that of Group B (Amlodipine). While in reducing Systolic Blood Pressure, Diastolic Blood Pressure and Mean Arterial Pressure both Groups shows highly significant result.

Discussion: All the ingredients of self formulated drug (*Vati*) basically have *Hridaya*, *Medhya*, *Mutrala*, *Vata Anulomaka*, *Nidrajanana* and *Raktadabashamaka* effect. Almost all the drugs have *Tridosahara* properties. The preparation mainly has *Tikta Kashaya Pradhana Rasa*, *Laghu*, *Snighda Guna*, *Sheeta Virya*, *Katu Vipaka* which helps in management of Hypertension.

Conclusion: The overall effect of Group A was better than Group B in relieving the symptoms while the effect of both groups in controlling Blood Pressure was similar. Moreover, no side effects were observed in patients during and after the treatment so, it can be concluded that the patients of Hypertension can be managed effectively by *Ayurveda* without fear of side effects as seen in Anti-hypertensive drugs.

Key Words: *Hypertension, Silent killer, Ayurveda, Essential Hypertension*



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INTRODUCTION

Cardiovascular Disease is one of life threatening gift of today's life. As per the report of WHO 2002, CVDs are likely to be the major cause of death and physical debility by 2020 in India. The most important risk factor for early onset and presentation of cardiovascular death is Hypertension. According to the latest Global Burden of Disease Study (2013), mortality burden due to high SBP in year 1990 was 6.95 million and increased to 10.36 million by the year 2013. Hypertension is an important problem in the scenario of public health, owing to its high prevalence. It is also known for its association with increased morbidity and mortality¹. Nearly 7.1 million lives are lost every year due to poor control of Hypertension. It is estimated that 1.56 billion people will suffer from Hypertension by 2025². A recent study showed that nearly 207 million people were found to be affected in India among which 112 million were men and 95 million were women³. Recent studies from India have shown the prevalence of Hypertension to be 25% in urban and 10% in rural population in India⁴.

E.H.T from the perspective of *Tridosha* is a *Vata Pradhana Tridoshaja Vyadhi*. Vitiated *Vata Dosh* is considered as the main factor because maintenance of *Dhatu (Rasa-Rakta) Gati* is done by *Vayu (Vyana Vayu)* itself⁶. *Vata* is also responsible for movement of other *Doshas (Pitta and Kapha)*. *Pitta* and *Kapha* compliment the effect of vitiated *Vata* and add to progression of disease. As *Vyana Vata* is responsible for the

movement of *Rasa-Rakta Dhatu*, any *Vaishamya* in *Vyana Vayu* will cause alteration in blood circulation. Considering its high prevalence and to explore a new combination of *Ayurvedic* herbs in modern era of ever growing Hypertension, an attempt was made in our project to find a reliable, cost effective and safe *Ayurvedic* medicine.

AIMS AND OBJECTIVES

- To study the etiopathogenesis of E.H.T on the basis of *Ayurvedic* parameters.
- To study the effect of *Ayurvedic* formulation in the management of E.H.T.
- To provide the reliable, cost effective *Ayurvedic* treatment for E.H.T.

HYPOTHESIS

H₀. *Ayurvedic* formulation has no effect on Essential Hypertension.

H₁. *Ayurvedic* formulation has some effect on Essential Hypertension.

MATERIALS AND METHODS

Total 60 **Patients** of Essential Hypertension were selected from the O.P.D. / I.P.D. department of Kayachikitsa, Rishikul Campus, Haridwar.

Ethical clearance- The research has been approved by the Institutional Ethical Committee. Written consent was taken from all the subjects before the trial and study was in accordance with ICH GCP Guidelines.

CTRI Number: CTRI/2018/04/013257
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SELECTION OF SAMPLE: - Randomized Sampling

TYPE OF STUDY: Single Blind

DURATION OF STUDY: 90 days

SELECTION OF DRUG

1. *Ayurvedic* formulation
2. Amlodipine

PREPARATION AND DOSE OF DRUG

1. *Ayurvedic* formulation in the form of *Vati* Preparation:

All the raw drugs i.e. *Jatamansi*, *Arjuna*, *Gokshura*, *Mandukaparni*, *Sarpagandha* and *Tagara* obtained from a renowned crude drug supplier (Sri Hans Pharmacy, Prem Nagar Ashram) from Haridwar, were identified & authenticated by the department of *Dravyaguna*, Rishikul campus, Uttarakhand Ayurved University, Haridwar. The drugs *Jatamansi*, *Arjuna*, *Gokshura*, *Mandukaparni* were taken in equal amount while *Sarpagandha* is taken one-fourth and *Tagara* is taken one-half. All the raw drugs were cleaned thoroughly with water and dried under sun to remove the moisture and later grinded to fine powder. After that drugs were grinded to *Yavkut* (coarse) *Churna*, and mixed with 8 part of water. The mixture was boiled till the proportion is reduced to one fourth of the principle quantity. This decoction was taken and *Bhawana* was given for 3 times (of each *Swarasa*) to the above prepared fine powder. The whole mixture was modified into tablet weighing 250mg each by using Gum acacia as binding material. The

tablets were packed in sterile polythene covers containing 60 tablets approximately each.

Dose: 2 BDS (500 mg) for three months with *Koshna Jal* as *Anupana* after meal.

2. Amlodipine:

Dose: 5mg once daily was given with luke warm water after meal.

DRUG TRIAL SCHEDULE:

The selected patients for trial were randomly divided into following 2 groups having 30 patients in each group.

GROUP A- Patients were treated with *Ayurvedic* formulation which is a self formulated combination.

GROUP B- Patients were treated with “Amlodipine”.

Assessment of the patients was done at the interval of 15 days and follow up was done 15 days after completion of treatment to look for any recurrence.

INCLUSION CRITERIA:

- Diagnosed patients without any complications were included.
- Age between 30 to 60 years.
- Irregularly treated patients for Hypertension.
- Blood pressure – up to Stage II (Moderate Hypertension)

Systolic blood pressure – 140-179 mmHg

Diastolic blood pressure – 90-109 mmHg

EXCLUSION CRITERIA:

- Patient having Hypertension due to other secondary disease.
- Renal disease



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- Due to other drugs
- Endocrinal diseases
- Coarctation of aorta
- Neurogenic causes
- Any other serious medical & surgically ill patients.
- Patient having complications of Hypertension.

CRITERIA FOR WITHDRAWAL:

1. Personal matter
2. Aggravation of complaints
3. Intercurrent illness
4. Any other difficulties
5. LAMA (patient leave against medical advice)

INVESTIGATIONS:

The following investigations were conducted to exclude other pathologies as well as to assess the condition of the patient.

Hb%, TLC, DLC, ESR, Fasting Blood Sugar, Lipid profile, S. Creatinine, Blood urea, S. Uric Acid, SGOT, SGPT, Urine – Routine & Microscopic

These investigations were done in all the patients before and after completion of treatment to rule out any other pathological condition.

PATHYA APATHYA:

All the patients in the trial were advised to reduce salt intake in their diet, avoid fatty and fried foods and include more vegetables and fruits in their diet, to stop addictions like smoking, alcohol if any and to do meditation for 30 minutes daily. The patients were given Diet Chart and also advised to

follow DASH Diet i.e. Dietary Approach to Stop HTN.

If patient was taking any drug therapy then he/she was advised to slowly taper off the dose and finally stop the drug 1 week before starting the trial.

RESULT

Effects of the therapies were compared before and after the treatment on the basis of self-formulated scoring scales based on subjective and objective parameters associated with the disease.

Table 1 Parameters of Assessment

SUBJECTIVE PARAMETERS	OBJECTIVE PARAMETERS
1. <i>Shiroruja</i> (Headache)	1. Systolic Blood Pressure
2. <i>Hridrava</i> (Palpitation)	2. Diastolic Blood pressure
3. <i>Klama</i> (Fatigue)	3. Pulse rate
4. <i>Bhrama</i> (Vertigo)	4. Pulse Pressure
5. <i>Akshiraga</i> (Redness of eyes)	5. Mean Arterial Pressure
6. <i>Krodhprachuryta</i> (Irritability/anger)	
7. <i>Alpanidra /Anidra</i> (Reduced sleep)	

STATISTICAL ANALYSIS

Wilcoxon Signed Rank Test was applied on the subjective parameters, described in Table No. 1, in both the Groups. **Paired t- test** was applied on Objective parameters described in Table No. 1. For inter Group comparison of subjective parameters **Mann-Whitney U test** was used. For inter Group comparison of objective & biochemical parameter, **Unpaired t- test** was used.

EFFICACY STUDY OF GROUP A ON BIOCHEMICAL VALUES:

In biochemical parameters, statistically Non Significant result was found in Hb%, TLC,



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Polymorphs, Lymphocyte, Eosinophills, Monocytes, Basophills, ESR and BSF. Among LFT & KFT, statistically Non significant result was found in SGOT, SGPT, B. Urea, S. Creatinine and Uric acid with $p > 0.05$. Among Lipid Profile, statistically significant result was found in Total Cholesterol, while Non-significant result was found in TGL, HDL, LDL and VLDL.

RESULTS

Table 2 Efficacy Study of Group A on Subjective Parameters

Subjective parameter	Median		Wilcoxon Signed Rank W	P- Value	% Effect	Result
	BT	AT				
1. <i>Shiroruja</i> (Headache)	3	1	231	<0.001	76.78%	HIGHLY SIGNIFICANT
2. <i>Hridadrava</i> (Palpitation)	2	1	91	<0.001	60.71%	HIGHLY SIGNIFICANT
3. <i>Klama</i> (Fatigue)	2	1	45	<0.01	42.8%	SIGNIFICANT
4. <i>Bhrama</i> (Giddiness)	2	0.5	105	<0.001	74.07%	HIGHLY SIGNIFICANT
5. <i>Akshiraga</i> (Redness of eyes)	1.5	0	10	>0.05	66.66%	NON SIGNIFICANT
6. <i>Krodha Prachuryta</i> (Irritability)	2	1	92	<0.001	60.71%	HIGHLY SIGNIFICANT
7. <i>Alpanidra / Anidra</i> (Reduced sleep)	2	0	105	<0.001	81.25%	HIGHLY SIGNIFICANT

In GROUP B (Amlodipine)

In subjective assessment, the result was statistically highly significant in *Shiroruja* and *Bhrama* with p value <0.001. Statistically significant result was found in *Hridadrava*, *Klama*, *Krodha Prachuryta* and *Alpanidra/Anidra* with p value <0.01 and <0.05. Non Significant result was found in *Akshiraga* with p value >0.05 as shown in Table No. 4.

In objective assessment, both groups shows statistically highly significant result was found in

Table 3 Efficacy Study of Group A on Objective Parameters

Objective parameters	Mean	N	SD	SE	t- value	p- value	Result
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While observing subjective and objective assessment following results are found:

In Group A (Ayurvedic formulation JAGMST)

In subjective assessment, the result was statistically highly significant in *Shiroruja*, *Hridadrava*, *Bhrama*, *Krodhaprachuryta* and *Alpanidra/Anidra* with p value <0.001 in each. Statistically significant result was found in *Klama* with p value <0.01 and Non Significant result was found in *Akshiraga* with p value <0.05 as shown in Table No. 2.

SBP, DBP and Mean Arterial Pressure. Statistically significant result was obtained in Pulse pressure. Non significant result was obtained in Pulse Rate.

On biochemical parameters, both groups shows insignificant changes in Hb%, TLC, DLC, ESR, BSF, SGOT, SGPT, B. UREA, S. CREATININE, Uric Acid and Lipid Profile with p value >0.05 as shown in Table No. 3,5.

INTER GROUP COMPARISSON:



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1.	SBP	BT	159.07	28	14.57	2.75	10.1	<0.001	HIGHLY SIGNIFICANT
		AT	125.71	28	11.68	2.20			
2.	DBP	BT	105.71	28	12.301	2.325	9.625	<0.001	HIGHLY SIGNIFICANT
		AT	80.714	28	8.133	1.537			
3.	Pulse Rate	BT	78.893	28	4.565	0.8627	2.029	>0.05	NON SIGNIFICANT
		AT	76.143	28	5.784	1.093			
4.	Pulse pressure	BT	53.357	28	10.612	2.005	3.070	<0.01	SIGNIFICANT
		AT	45	28	8.819	1.667			
5.	Mean Arterial Pressure	BT	122.91	28	11.572	2.187	9.518	<0.001	HIGHLY SIGNIFICANT
		AT	95.307	28	9.945	1.879			

Table 4 Efficacy Study of Group B on Subjective Parameters

Subjective parameter	Median		Wilcoxon Signed Rank W	p- Value	% Effect	Result
	BT	AT				
<i>Shiroruja</i> (Headache)	3	1	190	<0.001	50.87	HIGHLY SIGNIFICANT
<i>Hridadrava</i> (Palpitation)	3	2	120	<0.01	40	SIGNIFICANT
<i>Klama</i> (Fatigue)	2	1.5	36	<0.01	21.42	SIGNIFICANT
<i>Bhrama</i> (Giddiness)	2	1	171	<0.001	58.53	HIGHLY SIGNIFICANT
<i>Akshiraga</i> (Redness of eyes)	2	1	6	>0.05	66.66	NON SIGNIFICANT
<i>Krodha Prachuryta</i> (Irritability)	2	2	28	<0.01	31.03	SIGNIFICANT
<i>Alpanidra / Anidra</i> (Reduced sleep)	2	1	91	<0.01	52.94	SIGNIFICANT

Table 5 Efficacy Study of Group B on Objective Parameters

Objective parameters		Mean	N	SD	SE	t- value	p- value	Result
SBP	BT	157.19	27	15.445	2.972	12.956	<0.001	HIGHLY SIGNIFICANT
	AT	120.74	27	10.35	1.992			
DBP	BT	107.63	27	13.508	2.6	10.4	<0.001	HIGHLY SIGNIFICANT
	AT	79.259	27	9.168	1.764			
Pulse Rate	BT	78.815	27	6.822	1.313	0.5875	>0.05	NON SIGNIFICANT
	AT	79.48	27	4.353	0.837			
Pulse pressure	BT	49.185	27	13.915	2.678	2.514	<0.01	SIGNIFICANT
	AT	41.481	27	6.015	1.158			
Mean Arterial Pressure	BT	123.86	27	12.478	2.401	13.194	<0.001	HIGHLY SIGNIFICANT
	AT	93.048	27	9.147	1.760			

On symptom of *Hridadrava*, *Klama*, *Bhrama*, *Akshiraga* and *Krodha Prachuryta* insignificant result ($p>0.05$) was obtained while *Shiroruja* and *Alpanidra* shows significant result on comparing Group A and Group B as shown in Table No.6 . On SBP, DBP, Pulse Rate, Pulse Pressure and

Mean Arterial pressure, statistically insignificant result ($p>0.05$) was obtained on comparison of Group A and Group B as shown in Table No. 7. This shows that both the groups have similar effect in controlling Blood Pressure.



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On comparative assessment of % Relief in to Group B as shown in Table No. 8. In Objective Subjective parameters it was found that Group A parameters, Group B shows more % Relief than more relief in Subjective parameters as compared Group A as shown in Table No. 9.

EFFICACY STUDY OF GROUP B ON BIOCHEMICAL PARAMETERS:

Same result was obtained as of Group A which is described earlier.

Table 6 Intergroup Comparison of Subjective Parameter

Subjective parameters	Group	N	Mean	Sum of Ranks	Mann Whitney U	P value	Result
<i>Shiroruja</i> (Headache)	Group A	21	2.048	558.50	114	<0.01	SIGNIFICANT
	Group B	21	1.381	345			
<i>Hridadrava</i> (Palpitation)	Group A	15	1.2	263.5	111.5	>0.05	NON SIGNIFICANT
	Group B	17	1.059	264.5			
<i>Klama</i> (Fatigue)	Group A	11	1.182	113.50	40.50	>0.05	NON SIGNIFICANT
	Group B	8	1.125	76.50			
<i>Bhrama</i> (Giddiness)	Group A	14	1.5	246	111	>0.05	NON SIGNIFICANT
	Group B	18	1.33	282			
<i>Akshiraga</i> (redness of eyes)	Group A	4	1.250	15.50	5.50	>0.05	NON SIGNIFICANT
	Group B	3	1.333	12.50			
<i>Krodha Prachuryta</i> (Irritability)	Group A	15	0.9333	225.5	74.5	>0.05	NON SIGNIFICANT
	Group B	12	0.75	152.50			
<i>Alpanidra / Anidra</i> (Reduced sleep)	Group A	14	1.857	249	52	<0.05	SIGNIFICANT
	Group B	14	1.286	157			

Table 7 Intergroup Comparison of Objective Parameter

Parameters	Group	N	Mean	SD	SE	t value	p value	Result
Systolic blood pressure	Group A	28	33.35	17.47	3.302	0.7095	>0.05	NON SIGNIFICANT
	Group B	27	36.444	14.616	2.813			
Diastolic blood pressure	Group A	28	25	13.744	13.744	0.8953	>0.05	NON SIGNIFICANT
	Group B	27	28.37	14.175	14.175			
Pulse rate	Group A	28	2.75	7.173	1.356	1.926	>0.05	NON SIGNIFICANT
	Group B	27	-0.667	5.897	1.135			
Pulse pressure	Group A	28	8.357	14.402	2.722	0.1597	>0.05	NON SIGNIFICANT
	Group B	27	7.704	15.920	3.064			
Mean arterial pressure	Group A	28	27.604	15.346	2.9	0.8578	>0.05	NON SIGNIFICANT
	Group B	27	30.811	12.134	2.335			

OVERALL EFFECT OF THERAPY

Overall response in Group A (Ayurvedic formulation) was **Excellent** improvement in **28.57%** patients, **Marked** improvement in **57.14%** patients and **Mild** improvement in **3.57%**

patients whereas 10.7% patients showed no improvement. While Group B (Amlodipine) showed **Excellent** improvement in **7.4%** patients, **Marked** improvement in **44.44%** patients and **Mild** improvement in **40.7%** whereas 3.7%



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patients showed no improvement as shown in Table No. 10.

Table 8 Comparative Assessment of % Relief in Subjective Parameters

Symptoms	% Relief in Group A	% Relief in Group B
<i>Shiroruja</i> (Headache)	76.78	50.87
<i>Hridadrava</i> (Palpitation)	60.71	40
<i>Klama</i> (Fatigue)	42.8	21.42
<i>Bhrama</i> (Giddiness)	74.07	58.53
<i>Akshiraga</i> (redness of eyes)	66.66	66.66
<i>Krodha Prachuryta</i> (Irritability)	60.71	31.03

Table 10 Estimation of Overall Response in Each Group

Improvement (%)	Group A		Group B	
	No	%	No	%
Excellent (75-100%)	8	28.57%	2	7.4%
Marked Improvement (50-74%)	16	57.14%	10	37%
Mild Improvement (25-49%)	1	3.57%	13	48.14%
No Improvement (<24%)	3	10.7%	2	7.4%

DISCUSSION

Probable Mode of Action of Ayurvedic formulation:

Maximum drugs of combination are having *Tikta Kashaya Pradhana Rasa; Laghu, Snighda Guna; Sheeta Virya; Katu Vipaka*. The overall effect of the combination is *Tridosha Hara*. The effect of *Jatamansi* is *Medhya, Nidrajanana* and *Hridaya Niyamaka*. *Arjuna* is *Hridaya, Rakta Prasadaka, Shothahara* and *Medohara*. *Gokshura* is *Mutrala, Vata Anulomka* and *Shothahara*. *Mandukaparni* is *Medhya, Hridaya* and *Ama Pachaka*. *Sarpagandha* is *Raktadaba Shamaka, Nidrajanana* and *Ama Pachaka* and *Tagara* is *Nidrajanana, Medhya, Hridaya, Mutrala* and *Deepana Pachana*. The various properties of combination like *Medhya, Hridaya, Vata Anulomaka, Ama Pachaka* and *Nidrajanana* etc.

<i>Alpanidra / Anidra</i> (Reduced sleep)	81.25	52.94
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Table 9 Comparative Assessment of % Relief in Objective Parameters

Parameters	% Relief in Group A	% Relief in Group B
Systolic blood pressure	20.97	23.186
Diastolic blood pressure	23.65	26.35
Pulse rate	3.48	0.8
Pulse pressure	15.66	15.66
Mean arterial pressure	22.45	24.87

helps in controlling the factors responsible for the Blood Pressure to rise. Therefore the combination helps in the management of Essential Hypertension by breaking the *Samprapti*.

Probable Mode of Action of Amlodipine:

It is an angio-selective Calcium Channel Blocker and inhibits the movement of calcium ions into vascular smooth muscle cells and cardiac muscle cells which inhibits their contraction. This causes vaso-dilation and a reduction in peripheral vascular resistance, thus lowering blood pressure. Its effects on cardiac muscle also prevent excessive constriction in the coronary arteries⁷. Amlodipine reduces the total peripheral resistance (after load) against which the heart works and reduces the rate of pressure production, thereby lowering myocardial oxygen demand, at any given level of exercise⁸.



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CONCLUSION

Essential hypertension can be correlated as *Vata Pradhana Tridoshaja Vyadhi*. Stress is most powerful factor for causing Essential Hypertension. High intake of salt and tea, sedentary lifestyle, Lack of exercise precipitate the disease. Overall effect of *Ayurvedic* formulation can be summarized as *Tridosha Shamaka* (mainly *Vata*), *Manasa Doshahara*, *Hridya*, *Medhya* and *Mutrala*. Due to wider range of action, the *Ayurvedic* formulation thus prepared has shown better results in relieving the symptoms of Hypertension. In lowering the Blood Pressure, satisfactory result was obtained from the preparation. Moreover no side effects were observed in patients during and after the treatment so, it can be concluded that the patients of Hypertension can be managed effectively by *Ayurveda* without fear of side effects.

CONFLICT OF INTEREST

None



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