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### **Research Article**

# CLINICAL STUDY TO EVALUATE THE EFFICACY OF *PUNARNAVA CHURNA* ON *VYANA BALA VAISHAMYA* (HYPERTENSION)

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#### ABSTRACT

In essential hypertension, mainly Vata prakopa occurs, particularly Vyana vata as it is responsible for Rasa- rakta samvahana. By virtue of its Ruksha, Sheeta and Khara guna, Rasa-rakta vahini dhamanis are constricted, also its Ruksha guna dries the Malarupa kapha at the inner side of the vessels making them more rigid (Kathin). Vascular lumen may be reduced further leading to obstruction in it. So, for normal circulatory function, increased force of Vyana vayu is required resulting into Vyana bala Vaishamya and hence leading to the development of hypertension. The WHO rates hypertension as one of the most important causes of premature death worldwide. Worldwide, approximately 1 billion people have hypertension, contributing to more than 7.1 million deaths per year. The number of adults with hypertension in 2025 is predicted to increase by about 60% to a total of around 1.56 billion. In India, Cardiovascular diseases caused 2.3 million deaths in the year 1990; this is projected to double by the year 2020. Numbers of drugs are available in modern medicine to treat the disease in its symptomatically active state but still are unable to cure the hypertension. Hyper function of Vyana is considered under Vyana Bala Vaishamya which produces increased force in the wall of the channels (blood vessels) to produce the disease hypertension. In the present clinical trial 'Punarnava Churna' is orally administered for 1 month twice a day after food. 30 clinically diagnosed patients of hypertension were randomly selected and divided into two groups. BP, CBC, RBS, ECG, Blood urea, Serum creatinine and Lipid profile were done before and after the clinical trial. After completion of study signs and symptoms were controlled significantly and also there were significant changes in laboratory findings.

**KEYWORDS:** Hypertension, Rasa- rakta samvahana, Vyana Bala Vaishamya, Vyana, Punarnava Churna.

#### INTRODUCTION

Hypertension (HTN or HT), also known as high blood pressure or arterial hypertension, is a chronic medical condition in which the blood pressure in the arteries is persistently elevated.<sup>[1]</sup> Hypertension is common disorder rising in incidence and once established treatment is obligatory. It is growing in incidence globally particularly in developing countries.<sup>[2]</sup> The WHO rates HTN as one of the most important causes of premature death worldwide.<sup>[3]</sup>

Overall, approximately 20% of the world's adults are estimated to have hypertension, when hypertension is defined as BP in excess of 140/90mm Hg. The number of adults with hypertension in 2025 is predicted to increase by about 60% to a total of around 1.56 billion. In India, Cardiovascular diseases caused 2.3 million deaths in the year 1990; this is projected to double by the year 2020. Hypertension is directly responsible for 57% of all stroke deaths and 24% of all coronary heart disease deaths in India.

*Vvana* is a type of *Vata* which moves all over the body. Its *Nirukti* indicates that it affects the whole body. Bala here is an indicative of the normal Guna (properties) and Karma (functions) of Vyana. Vaishamva refers to Vikriti or disequilibrium of dosha in which they are able to produce the disease. As per (Ch. Sha. 6/4,) Vaishamya means Vrddhi or Hrasa, i.e., either increase or decrease. Therefore, Vyana Bala Vaishamya may either be considered as increased or decreased function of *Vvana*. But, it is also mentioned that the decreased *Dosha* is not able to manifest its own symptoms.<sup>[4]</sup> So, the decreased *Dosha* may not be able to produce any disease. Hence, in the present study, hyper-function of Vyana Vata is considered under Vyana Bala Vaishamya which produces increased force in the wall of the channels (blood vessels) to produce the disease 'Hypertension'.

In essential hypertension, mainly *Vataprakopa* occurs, particularly *Vyana Vata* as it is responsible for *Rasarakta sanvahana*. By virtue of its *Ruksha, Sheeta* and *Khara Chala, Rasa-raktavahini dhamanis* are constricted, also its *Ruksha Chala* dries the *Mala rupa kapha* at the inner side of the vessels making them more rigid (*Kathin*). Vascular lumen may be reduced further leading to obstruction in it. So, for normal circulatory function, there is increased force of *Vyana. Vyana* is required resulting into *Vyana Bala Vaishamya* and hence leading to the development of hypertension.

The assessment of effects of *Punarnava Churna* in the patients of hypertension was the chief objective of the study along with the replacement of the modern anti- hypertensive drugs by a safe and effective alternative in Ayurveda.

#### **AIMS AND OBJECTIVES**

To conduct an *Upashyatmaka* (randomized trial) to assess the efficacy of *Punarnava Churna* (*Boerhavia diffusa*) on *Vyana Bala Vaishmya* (Hypertension).

#### **MATERIALS AND METHODS**

**Study site:** Laboratory / OPD / IPD of NIA hospitals, Jaipur and certain NIA camp sites.

#### **Selection of patients**

For the clinical study, 30 subjects of hypertension clinically diagnosed and randomly selected from the OPD/IPD of N.I.A, Jaipur, after excluding the drop outs and cases that did not fulfill the criteria of diagnosis. Subjects were given drug *Punarnava Churna (Boerhavia diffusa)* daily for 30 days in the dose of 2gms twice a day. After complete the trial, results before treatment and after treatment were compared and analyzed statistically.

#### **Inclusion Criteria**

- 1] Patients willing to sign the consent form for the clinical trial.
- 2] Either sex or age group above 18 yrs.
- 3] Patients of Hypertension (JNC <sup>8th</sup> Criteria.)

#### **Exclusion Criteria**

1] Known case of Renal diseases, Diabetic Mellitus

2] Pregnancy induced hypertension

3] History of drugs like Oral Contraceptive Pills, steroids.

4] Known case of Ventricular hypertrophy, Secondary hypertension, hypertension with severe complication.

5] Known case of Portal hypertension

6] Renal artery stenosis induced hypertension.

### **Diagnostic Criteria**

• History, clinical examination, systemic examination according to specially prepared CRF incorporating Ayurveda parameters of *Dashvidha pariksha* and all the signs and symptoms of disease etc.

• Laboratory parameters- BP, CBC, RBS, ECG, Blood urea, Serum creatinine and Lipid profile.

#### Plan of the Study

The present trial was randomized. 30 subjects of hypertension were clinically diagnosed. They were treated with drug *Punarnava Churna* (*Boerhavia diffusa*) daily for 30 days in the dose of 2gms twice a day. At the end of the treatment, efficacy of the drug was statistically analyzed.

#### **Assessment of Disease**

Assessment of the blood pressure was done by measuring it with the help of its measuring device, sphygmomanometer and was observed after each follow up for its measurement. The relative extent of all these criteria was recorded according to the rating scale in each patient at the initial stage and subsequent follow-ups.

#### **Data Documentation and Statistical Analysis**

Data collected in various stages of the clinical trial were analyzed using Graph Pad Instat (version 3.10, 32 bit for windows created July 10, 2009).

#### Parameters of assessment of symptoms

(1) Severity scoring of *Sirahshula* (headache) 0 = No headache.

1 = Occurs rarely, relieves without medications.

2 = Occurs only when subjected to stress and exertion.

3 = frequently present and relieves with medications but not interfering with daily activities.

4 =Persistent headache, not cure even on medications, also interfering with daily activities.

#### (2) Severity scoring of Hritdrava (Palpitation)

- 0 = No palpitation
- 1 = Palpitation caused by vigorous physical exercise.
- 2 = Caused by moderate physical exercise.
- 3 = on daily routine work.
- 4 = Even at rest also.

#### (3) Severity scoring of Bhrama (Dizziness)

- 0 = Not present at all.
- 1 = rarely present.
- 2 = occasionally present but only on movement.
- 3 = frequently present for some moment even in sitting condition.

4 = Present even on lying condition and patient is unable to hold himself without any support.

#### (4) Severity scoring of *Klama* (Easy fatigability) 0 = Never

- 1 = after heavy physical work.
- 2 = after moderate physical work.
- 3 = Easy fatigability even on daily routine work.
- 4 = Even on rest.

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(5) Severity scoring of Anidra	4 = Persistent and associated with undue thirst
(Insomnia/disturbed sleep)	(10) Severity scoring of <i>Smritinash</i> (Impaired
0 = Sound sleep.	memory) 0 = Absent.
1 = occasionally awakenings at night.	1 = Rarely Present.
2 = Disturbed sleep, wake up 1-2 times at night.	2 = occasionally present for a short time but reminds
3 = Very less sleep in small intervals making patient	it sooner.
irritable.	3 = frequently present for a long time but reminds it
4 = Not getting sleep without medicine.	later on.
(6) Severity scoring of <i>Raktang akshita</i> (Redness of eyes)	4 = persistently present and doesn't remind later also.
0 = Nil	(11) Severity scoring of <i>Kampa</i> (Tremors)
1 = rarely and mild redness remains only for small	0 = Absent.
duration.	1 = rarely present only on some vigorous physical
2 = frequently and mild / moderate redness remains	exercise.
for 2 -3 hrs.	2 = Present on slight physical or mental exertion.
3 = Often and moderate / severe redness remains for longer duration.	3 = Present even on doing daily routine work and with mild exertion.
4 = Continuous and moderate / severe redness nearly	4 = at rest also.
always present.	(12) Severity scoring of <i>Daurbalya</i> (Weakness)
(7) Severity scoring of Krodha prachurata (Loss of	0 = Absent.
patience)	1 = occasionally present.
0 = Normal.	$\sqrt{2}$ = frequently present but only for some short
1 = rarely angry by major provocation and for very	duration.
short duration.	3 = Always present but not interfering with daily
2 = rarely angry by moderate to major provocation	activi <mark>ties</mark> .
for long duration.	4 = Always present interfering with daily.
3 = Often angry by mild to major provocation for short duration.	Assessment of results
4 = Continuous angry and irritable.	• Assessment Criteria for effect of treatment on
(8) Severity scoring of Swasakritchata	pre blood pressure
(Dyspnoea)	To calculate the percentage relief in blood pressure,
0 = Absent.	mean BP of patients of both the times, i.e. before treatment and after treatment, of each group was
1= Present on severe exertion	observed and percentage relief was calculated at the
2 = Present on moderate exertion	end by using the below given formula;
3 = Present on mild exertion	Percentage relief in Systolic Blood Pressure =
4 = Present even on rest	Mean of BP (BT) - Mean of BP (AT) x 100
(9) Severity scoring of <i>Bahumutrata</i> (Polyuria)	Mean of BP (BT)
0 = Absent.	Percentage relief in Diastolic Blood Pressure =
	Mean of BP (BT) - Mean of BP (AT) x 100
<ul><li>1 = occasionally present</li><li>2 = Present only in daytime</li></ul>	Mean of BP (BT)
3 = Persistent but not associated with undue thirst	
Trial Drugs	

Drug	Botanical name	Rasa	Guna Virya		Vipaka	Doshakarma	
Punarnava	Boerhavia diffusa	Madhura, Tikta, Kashaya	Laghu, Ruksha	Ushna	Madhura	Vatashlaishmahara	

# Table 1: Rasa panchak of Punarnava<sup>[5]</sup>

Table 2: For subjective (non-parametric) variables										
S.No.	Symptoms	Mean (n=30)			%	S.D.	S.E	ʻp'	Result	
		B.T.	A.T.	Diff.	Change	(±)	(±)	Value		
1.	Sirahshula	2.53	1.10	1.43	56.58	0.77	0.14	0.0012	VS	
2.	Hritdrava	2.77	1.33	1.43	51.81	0.82	0.15	< 0.0001	VS	
3.	Bhrama	2.13	1.53	0.60	28.13	0.89	0.16	< 0.0001	VS	
4.	Klama	2.30	2.43	-0.13	-5.80	1.89	0.34	0.1390	NS	
5.	Anidra	2.47	1.20	1.27	51.35	1.01	0.19	< 0.001	VS	
6.	Raktangakshita	5.01	4.99	0.02	0.40	1.68	0.31	0.0416	S	
7.	Krodhaprachuryata	2.47	1.00	1.47	59.46	0.73	0.13	< 0.0001	VS	
8.	Svashkrichhata	2.33	1.03	1.30	55.71	0.84	0.15	< 0.0001	VS	
9.	Bahumutrata	2.20	1.10	1.10	50.00	0.76	0.14	< 0.0001	VS	
10.	Smratinash	5.11	4.23	0.89	17.34	0.92	0.17	< 0.0001	VS	
11.	Катра	5.35	4.36	0.99	18.45	0.94	0.17	< 0.001	VS	
12.	Daurbalya	2.73	1.57	1.17	42.68	0.79	0.14	< 0.001	VS	

### Table 2: For subjective (non-parametric) variables

Wilcoxon Matched Pair Signed Rank Test in individual group comparing before and after scores.

Table 3: For objective (parametric) variables

S.No.		Mean (n=30)			urven es	S.D.	S.E	'ť	ʻp'	Result
	Symptoms	B.T.	A.T.	Diff.	Change	(±)	(±)	value	Value	
1.	Pulse	80.07	79.37	0.70	0.87	5.07	0.92	0.76	0.4989	NS
2.	B.P.(systolic)	142.67	131.87	10.80	7.57	11.60	2.12	5.10	< 0.0001	VS
3.	B.P.(diastolic)	91.40	85.60	5.80	6.35	6.29	1.15	5.05	< 0.0001	VS
4.	RBS	115.13	114.97	0.17	0.14	20.37	3.72	0.04	0.1272	NS
5.	TLC	6630.33	6563.33	67.00	1.01	272.58	49.77	1.35	0.1927	NS
6.	Blood urea	39.93	39.10	0.83	2.09	5.55	1.01	0.82	0.4178	NS
7.	Sr.creatinine	1.97	1.94	0.03	1.52	0.21	0.04	0.78	0.4445	NS
8.	Sr.cholesterol	208.73	204.90	3.83	1.84	16.92	3.09	1.24	0.1372	NS
9.	Sr.triglyceride	167.78	166.56	1.22	0.73	20.28	3.70	0.33	0.5804	NS
10.	HDL	85.28	84.29	0.99	1.16	4.98	0.91	1.08	0.0540	NS
11.	LDL	92.70	91.50	1.20	1.29	4.08	0.74	1.61	0.0101	S
12.	VLDL	33.45	33.29	0.15	0.46	2.75	0.50	0.31	0.0771	NS

Paired t test (P = Two tailed 'p' value) - in individual group comparing before and after measurements **Discussion on Effect of Treatments** 

## on Chief Complaints

**OBSERVATION** 

*Punarnava Churna* showed better improvement in *Krodhaprachuryata* (59.46%), *Daurbalya* (42.68%), *Anidra* (51.35%), *Hritdrava* (51.81%), *Svashkrichhata* (55.71%), and *Bahumutrata* (50%). They all showed statistically extremely significant result. Since, the trial drug is having *Madhur rasa* properties, so significant result has been found in the above said complaints. It was found that *Punarnava Churna* had better results on *Daurbalya, Anidra, Hritdrava, Svashkrichchhata, Bahumutrata* and *Krodha Prachurata.* 

# Probable Modes of Action of '*Punarnava*' on Symptoms produce in Hypertension

It might have relieved the symptom *Shirshula* which is found most commonly in hypertension due to its *Shirshula* and *Madhura, Tikta Rasa* property

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Shirshula and hypertension both have Pittadosha as dominant Dushya as Punarnava is said to be Madhura, Tikta rasa property (Pittshamaka). Same might be the reason of its effect on Raktangakshita as Pitta is predominantly involved in these features. It might have relieved in Kampa due to its property of Vataprashamana.

The trial drug possess *Rasayana* property by which it helps in relieving stress, anxiety giving stability to mind which might be the reason of getting relief by it in Anidra and Krodhprachuryta. Being a Rasavana, it might have improved in Smritinash. Madhura Rasa of drug causes Pittashamak. Madhura rasa by its Prahladana auna increases the Oia in the body and thus regulates the circulatory function of heart by reducing *Chala guna* of *Vata*. The drug also possesses the property of Mutral and Balva, that's why it might have relieved in the symptoms Hritdrava and Svashkrichhata. The drug is having *Deepan* property which helps to alleviate obstruction in the *Srotas* due to *Aam* by its digestion and thereby resulting into Srotoshodhana and Vatanulomana. This might have the reason of its relief in Klama.

It is also having the property of *Balya* and it is also said to be used in *Daurbalya* as its *Rogaghnata*. That is why it must have helped in getting relief in *Daurbalya*. *Rasayana* drugs also possess the property of *Srotoshodhana* which makes them useful where the *Samprapti* of disease is due to *Avarana* i.e., due to *Margavrodha*, as the same happens in hypertension.

#### Discussion Regarding Effect of Therapy on Blood Pressure

• **Systolic Blood Pressure-** In the study, an average of 7.57% decrease was noticed, respectively which was considered statistically extremely significant in the cases.

• **Diastolic Blood Pressure-** In the study, an average of 6.35% decrease was noticed, respectively which was considered statistically extremely significant in the cases.

# Probable Modes of Action of Drug '*Punarnava*' on the Blood Pressure

The drug is having *Deepan* property which helps to alleviate obstruction in the *Srotas* due to *Aam* by its digestion and thereby resulting into *Srotoshodhana* and *Vatanulomana*. Destruction of *Srotorodha* regulates the movements of *Vata* in its normal direction through the micro channels. Thus, the drug may be effective where pathogenesis of the disease involves obstruction i.e., vitiation of *Vata* due to its *Margavrodha*, which also applies on hypertension. Hence the trial drug having *Ushna virya*, it mainly acts on vitiated *Vata dosha* and thereby also helps to alleviate the *Samprapti* of disease. The drug also helps in the breaking of etiopathogenesis of the disease at the level of *Tridosha* by its property of *Tridoshhara* as in essential hypertension. The drug might have reduced the blood volume resulting into decreased blood pressure due to its *Mutral* property. *Tikta rasa* may act on *Rasavaha, Raktavaha* and *Medovaha Srotas* by its *Shothahara, Deepan, Pachan* property. It absorbs excess *Kleda, Sweda, Kapha, Pitta* in the body by its *Pachan* property and helps in reducing blood volume.

Hence, we can say that the significant result produced by *Punarnava Churna* in *Vyana Bala Vaishamya* i.e., hypertension may be due to its *Balya* effect thereby producing anxiolytic, antistress, CNS depressant effect by inhibiting noradrenergic sympathetic nerves supplying to the heart. Through its *Pachan, Mutral, Vatanulomana* properties, it relieved *Srotorodha* and does digestion of *Aam* and also decreases blood volume which it may have contributed to decrease in blood pressure.

#### Discussion on Effect of Treatments on the Lab Investigations

(1) Random Blood Sugar- In the study, an average of 0.14% decrease was noticed, respectively which was considered statistically not significant in the cases.

(2) Blood urea- In the study, an average of 2.09% decrease was observed, respectively which was considered statistically not significant in both the cases.

(3) Serum Creatinine- In the study, an average of 1.52% decrease was observed, respectively which was considered statistically not significant in the cases.

**(4) Serum Cholesterol-** In the study, an average of 1.84% decrease was observed, respectively which was considered statistically extremely significant in the cases.

**(5) Serum Triglycerides-** In the study, an average of 0.73% decrease was observed, respectively which was considered statistically not significant.

**(6) HDL-** In the study, an average of 1.16% decrease was observed, respectively which was considered statistically very significant.

**(7) LD-** In the study, an average of 1.29% decrease was observed, respectively which was considered statistically not significant in the cases.

**(8) VLDL-** In the study, an average of 0.46% decrease was observed, respectively which was considered statistically not significant in the cases.

**(9) TLC-** In the study, an average of 1.01% decrease was observed, respectively which was considered statistically significant.

#### CONCLUSION

- 1. *Punarnava Churna* showed statistically extremely significant results in various sign and symptoms of *Vyana Bala Vaishamya.*
- 2. In *Punarnava Churna* showed statistically highly significant results in *Bahumutrata, Krodha pracuryata, Klama, Bhram.* It showed statistically significant result in LDL but statistically non significant results in blood urea, HDL.
- 3. From the results obtained *Punarnava Churna*, it can be concluded that therapy *Punarnava Churna* is a safe and effective Ayurvedic treatment of *Vyana Bala Vaishamya* (Hypertension).

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