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.[1] Hypertension is common disorder rising in incidence and once established treatment is obligatory. It is growing in incidence globally particularly in developing countries.[2] The WHO rates HTN as one of the most important causes of premature death worldwide.[3]

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.

Vyana 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. Vaishamya refers to Vikriti or disequilibrium of dosha in which they are able to produce the disease. As per (Ch. Sha. 6/4,) Vaishamya means Vrdhhi or Hrasa, i.e., either increase or decrease. Therefore, Vyana Bala Vaishamya may either be considered as increased or decreased function of Vyana. But, it is also mentioned that the decreased Dosha is not able to manifest its own symptoms.[4] 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 Vata-prakopa occurs, particularly Vyana Vata as it is responsible for Rasarakta samvahana. 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 Vaishamya (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 8th Criteria.)

Exclusion Criteria
1] Known case of Renal diseases, Diabetic Mellitus
2] Pregnancy induced hypertension
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
- Laboratory parameters- BP, CBC, RBS, ECG, Blood urea, Serum creatinine and Lipid profile.
- 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.

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 routine work.
4 = Even on rest.
(5) Severity scoring of Anidra (Insomnia/disturbed sleep)
0 = Sound sleep.
1 = occasionally awakenings at night.
2 = Disturbed sleep, wake up 1-2 times at night.
3 = Very less sleep in small intervals making patient irritable.
4 = Not getting sleep without medicine.

(6) Severity scoring of Raktang akshita (Redness of eyes)
0 = Nil
1 = rarely and mild redness remains only for small duration.
2 = frequently and mild / moderate redness remains for 2-3 hrs.
3 = Often and moderate / severe redness remains for longer duration.
4 = Continuous and moderate / severe redness nearly always present.

(7) Severity scoring of Krodha prachurata (Loss of patience)
0 = Normal.
1 = rarely angry by major provocation and for very short duration.
2 = rarely angry by moderate to major provocation for long duration.
3 = Often angry by mild to major provocation for short duration.
4 = Continuous angry and irritable.

(8) Severity scoring of Swasakritchata (Dyspnoea)
0 = Absent.
1 = Present on severe exertion
2 = Present on moderate exertion
3 = Present on mild exertion
4 = Present even on rest

(9) Severity scoring of Bahumutrata (Polyuria)
0 = Absent.
1 = occasionally present
2 = Present only in daytime
3 = Persistent but not associated with undue thirst

Trial Drugs

<table>
<thead>
<tr>
<th>Drug</th>
<th>Botanical name</th>
<th>Rasa</th>
<th>Guna</th>
<th>Virya</th>
<th>Vipaka</th>
<th>Doshakarma</th>
</tr>
</thead>
<tbody>
<tr>
<td>Punarnava</td>
<td>Boerhavia diffusa</td>
<td>Madhura, Tikta, Kashaya</td>
<td>Laghu, Ruksha</td>
<td>Ushna</td>
<td>Madhura</td>
<td>Vatashlaishmahara</td>
</tr>
</tbody>
</table>

(10) Severity scoring of Smritinash (Impaired memory)
0 = Absent.
1 = Rarely Present.
2 = occasionally present for a short time but reminds it sooner.
3 = frequently present for a long time but reminds it later on.
4 = persistently present and doesn’t remind later also.

(11) Severity scoring of Kampa (Tremors)
0 = Absent.
1 = rarely present on some vigorous physical exercise.
2 = Present on slight physical or mental exertion.
3 = Present even on doing daily routine work and with mild exertion.
4 = at rest also.

(12) Severity scoring of Daurbalya (Weakness)
0 = Absent.
1 = occasionally present.
2 = frequently present but only for some short duration.
3 = Always present but not interfering with daily activities.
4 = Always present interfering with daily.

Assessment of results

- Assessment Criteria for effect of treatment on blood pressure

To calculate the percentage relief in blood pressure, mean BP of patients of both the times, i.e. before treatment and after treatment, of each group was observed and percentage relief was calculated at the end by using the below given formula;

Percentage relief in Systolic Blood Pressure = \( \frac{\text{Mean of BP (BT)} - \text{Mean of BP (AT)}}{\text{Mean of BP (BT)}} \times 100 \)

Percentage relief in Diastolic Blood Pressure = \( \frac{\text{Mean of BP (BT)} - \text{Mean of BP (AT)}}{\text{Mean of BP (BT)}} \times 100 \)
OBSERVATION

Table 2: For subjective (non-parametric) variables

<table>
<thead>
<tr>
<th>S.No.</th>
<th>Symptoms</th>
<th>Mean (n=30)</th>
<th>% Change</th>
<th>S.D. (±)</th>
<th>S.E (±)</th>
<th>'p' Value</th>
<th>Result</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>B.T.</td>
<td>A.T.</td>
<td>Diff.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1.</td>
<td>Sirahshula</td>
<td>2.53</td>
<td>1.10</td>
<td>1.43</td>
<td>56.58</td>
<td>0.77</td>
<td>0.14</td>
</tr>
<tr>
<td>2.</td>
<td>Hritdrava</td>
<td>2.77</td>
<td>1.33</td>
<td>1.43</td>
<td>51.81</td>
<td>0.82</td>
<td>0.15</td>
</tr>
<tr>
<td>3.</td>
<td>Brahma</td>
<td>2.13</td>
<td>1.53</td>
<td>0.60</td>
<td>28.13</td>
<td>0.89</td>
<td>0.16</td>
</tr>
<tr>
<td>4.</td>
<td>Klama</td>
<td>2.30</td>
<td>2.43</td>
<td>-0.13</td>
<td>-5.80</td>
<td>1.89</td>
<td>0.34</td>
</tr>
<tr>
<td>5.</td>
<td>Anidra</td>
<td>2.47</td>
<td>1.20</td>
<td>1.27</td>
<td>51.35</td>
<td>1.01</td>
<td>0.19</td>
</tr>
<tr>
<td>6.</td>
<td>Raktangakshita</td>
<td>5.01</td>
<td>4.99</td>
<td>0.02</td>
<td>0.40</td>
<td>1.68</td>
<td>0.31</td>
</tr>
<tr>
<td>7.</td>
<td>Krodhaprachuryata</td>
<td>2.47</td>
<td>1.00</td>
<td>1.47</td>
<td>59.46</td>
<td>0.73</td>
<td>0.13</td>
</tr>
<tr>
<td>8.</td>
<td>Svashkrichhata</td>
<td>2.33</td>
<td>1.03</td>
<td>1.30</td>
<td>55.71</td>
<td>0.84</td>
<td>0.15</td>
</tr>
<tr>
<td>9.</td>
<td>Bahumutrata</td>
<td>2.20</td>
<td>1.10</td>
<td>1.10</td>
<td>50.00</td>
<td>0.76</td>
<td>0.14</td>
</tr>
<tr>
<td>10.</td>
<td>Smratinash</td>
<td>5.11</td>
<td>4.23</td>
<td>0.89</td>
<td>17.34</td>
<td>0.92</td>
<td>0.17</td>
</tr>
<tr>
<td>11.</td>
<td>Kampa</td>
<td>5.35</td>
<td>4.36</td>
<td>0.99</td>
<td>18.45</td>
<td>0.94</td>
<td>0.17</td>
</tr>
<tr>
<td>12.</td>
<td>Daurbalya</td>
<td>2.73</td>
<td>1.57</td>
<td>1.17</td>
<td>42.68</td>
<td>0.79</td>
<td>0.14</td>
</tr>
</tbody>
</table>

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

Table 3: For objective (parametric) variables

<table>
<thead>
<tr>
<th>S.No.</th>
<th>Symptoms</th>
<th>Mean (n=30)</th>
<th>% Change</th>
<th>S.D. (±)</th>
<th>S.E (±)</th>
<th>'t' value</th>
<th>'p' Value</th>
<th>Result</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>B.T.</td>
<td>A.T.</td>
<td>Diff.</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1.</td>
<td>Pulse</td>
<td>80.07</td>
<td>79.37</td>
<td>0.70</td>
<td>0.87</td>
<td>5.07</td>
<td>0.92</td>
<td>0.76</td>
</tr>
<tr>
<td>2.</td>
<td>B.P.(systolic)</td>
<td>142.67</td>
<td>131.87</td>
<td>10.80</td>
<td>7.57</td>
<td>11.61</td>
<td>2.12</td>
<td>5.10</td>
</tr>
<tr>
<td>3.</td>
<td>B.P.(diastolic)</td>
<td>91.40</td>
<td>85.60</td>
<td>5.80</td>
<td>6.35</td>
<td>6.29</td>
<td>1.15</td>
<td>5.05</td>
</tr>
<tr>
<td>4.</td>
<td>RBS</td>
<td>115.13</td>
<td>114.97</td>
<td>0.17</td>
<td>0.14</td>
<td>20.37</td>
<td>3.72</td>
<td>0.04</td>
</tr>
<tr>
<td>5.</td>
<td>TLC</td>
<td>6630.33</td>
<td>6563.33</td>
<td>67.00</td>
<td>1.01</td>
<td>272.58</td>
<td>49.77</td>
<td>1.35</td>
</tr>
<tr>
<td>6.</td>
<td>Blood urea</td>
<td>39.93</td>
<td>39.10</td>
<td>0.83</td>
<td>2.09</td>
<td>5.55</td>
<td>1.01</td>
<td>0.82</td>
</tr>
<tr>
<td>7.</td>
<td>Sr.creatinine</td>
<td>1.97</td>
<td>1.94</td>
<td>0.03</td>
<td>1.52</td>
<td>0.21</td>
<td>0.04</td>
<td>0.78</td>
</tr>
<tr>
<td>8.</td>
<td>Sr.cholesterol</td>
<td>208.73</td>
<td>204.90</td>
<td>3.83</td>
<td>1.84</td>
<td>16.92</td>
<td>3.09</td>
<td>1.24</td>
</tr>
<tr>
<td>9.</td>
<td>Sr.triglyceride</td>
<td>167.78</td>
<td>166.56</td>
<td>1.22</td>
<td>0.73</td>
<td>20.28</td>
<td>3.70</td>
<td>0.33</td>
</tr>
<tr>
<td>10.</td>
<td>HDL</td>
<td>85.28</td>
<td>84.29</td>
<td>0.99</td>
<td>1.16</td>
<td>4.98</td>
<td>0.91</td>
<td>1.08</td>
</tr>
<tr>
<td>11.</td>
<td>LDL</td>
<td>92.70</td>
<td>91.50</td>
<td>1.20</td>
<td>1.29</td>
<td>4.08</td>
<td>0.74</td>
<td>1.61</td>
</tr>
<tr>
<td>12.</td>
<td>VLDL</td>
<td>33.45</td>
<td>33.29</td>
<td>0.15</td>
<td>0.46</td>
<td>2.75</td>
<td>0.50</td>
<td>0.31</td>
</tr>
</tbody>
</table>

Paired t test (P = Two tailed ‘p’ value) - in individual group comparing before and after measurements

Discussion on Effect of Treatments

on Chief Complaints

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, Svashkrichhata, Bahumutrata and Krodhaprachuryata.

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

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 Krodhprachurya. Being a Rasayana, it might have improved in Smritinash. Madhura Rasa of drug causes Pittashamak. Madhura rasa by its Prahladana guna increases the Oja 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 Balya, 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 Vatamolana. 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 Vatamolana. 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 Tridoshshara 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 Vana 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, Vatamolana 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.
(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 signs and symptoms of *Vyana Bala Vaishamya*.

2. In *Punarnava Churna* showed statistically highly significant results in *Bahumutrata*, *Krodha praecuryata*, *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).

REFERENCES


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