

## A COMPARATIVE CLINICAL STUDY OF HARITAKYADI CHURNA AND SARPAGANDHA CHURNA IN THE MANAGEMENT OF ESSENTIAL HYPERTENSION

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### ABSTRACT

Hypertension is condition not disease in which arterial blood pressure is chronically elevated & it occurs in continuous range. Blood pressure above systolic / diastolic i.e. 140/90 mmhg is mainly considered as hypertension.<sup>[1]</sup> Hypertension is a leading cause of cardiovascular disease. The age standardized prevalence at baseline is 74% for men and 70.2% for women. The lifelong and palliative treatment of HTN in western medicine includes many side effects. So, "The Whole World" is looking forward as hope, and hence this is an area where there is a lot of Scope for *Ayurveda* clinical researches. Thus considering it as Challengeable melody present project is selected, **Objective**-To assess the clinical efficacy of *haritakyadi churna* and *sarpagandha churna*,

**Material and Methods**-in this study 70 patients randomly selected from the 30 to 60 years age group with signs and symptoms observation and result-overall it was observed that percentage of relief, **Conclusion**-*haritakyadi churna* has significant effect in the management of essential hypertension.

**KEYWORDS:** Essential Hypertension, *Haritkyadi churna*, *Sarpagandha churna*.

## INTRODUCTION

*Ayurveda* is such a science which has specific principal on the basis of which it has developed its diagnostic approach is based on the involvement of *dosh dushya srotas* etc. In *Ayurveda*, there is no direct reference of essential hypertension given by *Acharya*; but according to *Acharya Charaka* naming of disease is not essential, importance lies in the removal of disease.<sup>[2]</sup> According to *tri dosha's* principal of *ayurveda* EHT is *Vatapradhan Tridoshaja Vyadhi*. Vitiated *Vata dosha* is main reason because *Dhatu (Ras) Gati* or *Vikshepan* (circulation) is done by *Vayu* itself, *Pitta* and *Kapha* compliment the effect of vitiating *Vata* and to progression of disease.<sup>[3]</sup> Considering psychosomatic aspect of Hypertension it can be said that *manas dosha Raja and Tama* are also important factors in EHT. Since *chinta, Bhay, Krodha* etc. *Manas bhavas* are etiological factors in EHT.<sup>[4]</sup> *Dushyaras, Raktadhatu* plays important role in pathogenesis of hypertension. The Symptomatology quoted under *Raktapradoshaj rogas* by *Acharya Charak* almost coincides with signs and symptoms of essential hypertension among those *bhrama (vertigo), nidranash (insomnia), shirshool (headache), hriddrav (palpitation), Malbaddhata (constipation), klama (exhaustion without any exertion)* are common symptoms.<sup>[5]</sup>

## Hetu (Causes)

Table no 1: *Hetu* (causes) of.

<i>Hetu</i>	<i>Aharaj</i> <sup>[6]</sup>	<i>Viharaj</i> <sup>[7]</sup>	<i>Manas</i> <sup>[8]</sup>
<i>Bhava</i>	<i>Guru, Snigdha, Lavana rasa Bhojan</i> <i>Abhishyandi Bhojan</i> <i>Seeta &amp; Ushna Bhojan</i> <i>Virrudhashan</i> <i>Adhyashan</i>	<i>Divaswap</i> <i>Ativyayam</i> <i>Avyayam</i> <i>Ratrijagran</i> <i>Irshya,</i> <i>Vega Dharan</i>	<i>Chinta</i> <i>Krodha</i> <i>Shoka</i>

**Aim-** To determine the efficacy of *Haritkyadi churna* in the treatment of Essential Hypertension patients.

## OBJECTIVES

**Primary** -To evaluate the clinical efficacy of *Haritakyadi churn* in the management of essential hypertension patients.

**Secondary** -To compare the clinical efficacy of *Haritakyadi churna* with that of *Sarpagandha churna*.

## MATERIAL AND METHODOLOGY

### Sours of data

- Patients selected from departmental opd
- *Ayurvedic* seminar magazines,journals,digital library
- The raw drug was collected from the market under the super vision of *dravyagun* and *rasashatra* specialist

### Method of collection of data

- **Sample source**-total 70 patients selected from *kayachikitsa opd*
- **Duration of Research Study**: 2 months
- **Design of study**-An open randomized control clinical study has been conducted in selected patients.
- **Group of patients**-Group A were made as a trial Group on *Haritkyadi churna*.Group B were made as a controlled group on *Sarpagnadha churna*.

### *Haritkyadi churna*<sup>[9]</sup>

**Table no.2: Phyarmacological properties and action of trail drug according to *Ayurveda* literature.**

<i>Drug</i>	<i>Latin Name</i>	<i>Rasa</i>	<i>Virya</i>	<i>Vipak</i>
<i>Haritaki</i> <sup>[10]</sup>	<i>Terminalia chebula</i>	<i>Madhur, Amla, Katu,Tikta, Kashaya.</i>	<i>Ushna</i>	<i>Madhur</i>
<i>Vacha</i> <sup>[11]</sup>	<i>Acorus calamus</i>	<i>Katu,Tikta</i>	<i>Ushna</i>	<i>Katu</i>
<i>Rasna</i> <sup>[12]</sup>	<i>Pluchea lanceolata</i>	<i>Tikta</i>	<i>Ushna</i>	<i>Katu</i>
<i>Pippali</i> <sup>[13]</sup>	<i>Piper longum</i>	<i>Katu</i>	<i>Anushna</i>	<i>Madhur</i>
<i>Pushakrmool</i> <sup>[14]</sup>	<i>Innula racemosa</i>	<i>Katu, tikta</i>	<i>Ushna</i>	<i>Katu</i>
<i>Shati</i> <sup>[15]</sup>	<i>Hedyachium spicatum</i>	<i>Katu, tikta, kashay</i>	<i>Ushna</i>	<i>Katu</i>
<i>Sunthi</i> <sup>[16]</sup>	<i>Zingiber officinale</i>	<i>Katu</i>	<i>Ushna</i>	<i>Madhur</i>

2)*Sarpagandha*<sup>[17]</sup> having following property.

***Sarpagandha***: Latin Name – *Rauwalfia serpentina*

**Family**- *Apocynaceae*

***Ras***-*Katu, Tikta.*

***Virya***-*Ushan.*

***Vipak***-*Katu.*

**Chemical Constituents**- *Rauwolfia* contains indole alkaloids, such as reserpine, serpentinine and ajmalicine.

**Drug manufacturing** – crude drugs were identified and collected from local market.

**Drug componentants-**

<i>Haritaki</i>	}	<b>All in equal amount</b>
<i>Vacha</i>		
<i>Rasna</i>		
<i>Pippali</i>		
<i>Pushakrmool</i>		
<i>Shati</i>		
<i>Sunthi</i>		

#### **Method of Selection of study subjects- Inclusion criteria**

- Patients newly detected cases of Essential Hypertension.
- Aged between 30 to 60 Yrs.
- Both sex
- Patients whose BP systolic ranges b/w 140-159mmof hg systolic ranges & Diastolic ranges b/w 90-99mmhg.

#### **Exclusion Criteria**

- Patients suffering from any other systemic disorders like DM, CRF, Neurological defect, which interfere with the course of treatment, was excluded.
- Pregnant Woman & lactating mother.
- Patients are on prolonged medication like corticosteroids are rejected.

#### **Withdrawal Criteria**

- 1) If any Complication arises during treatment the cases was liable for rejection.
- 2) If patient is not responding to treatment and aggravation of symptoms occurs, the patient was referred to modern medicine as and when required for consultation.

**Investigation:-**Following investigation was done to rule out any complication, any subordinate disease or any dependence of disease.

HB%, BSL, ECG, urine routine, microscopic, was done.

Lipid profile if necessary

**Observation period-** On 0day, 8<sup>th</sup> day, 15<sup>th</sup> day, 22<sup>th</sup> day, 30<sup>th</sup> day during study period of 30 days, subject was asked for visit to note the relief in the symptoms.

**Follow Up:** 2 weeks after the treatment.

### Management of Groups

**Table no-3: Drug management.**

	<b>Trial Group</b>	<b>Controlled Group</b>
Drug	<i>Haritakyadi churna</i>	<i>Sarpagandha churna</i>
Dose	5gm orally twice daily after meal.	5gm orally twice daily after meal.
<i>Anupan</i>	<i>Koshna Jal</i>	<i>Koshna Jal</i>
Duration	2 month	2 month

### Method of data Collection relevant to objective

A. **Subjective criteria-** *Shirshool, Bhrama, Klama, Nidranash, Hriddrav, Malbaddhata.*

### Following were Assessment Criteria

#### 1) *Shirshool* (Headache)

- Absent :1: Normal
- Mild degree of *shirshoola* : 2 :Occasional for short duration.
- Moderate degree of *shirshoola*: 3 :moderate inter mitten, not affect daily routine.
- Severe degree of *shirshoola*:4 :severe frequent affecting daily routine.

#### 1) *Bhrama* (vertigo)

- Absent :1: Normal
- Mild degree of *bhrama* :2: 2-3times per week.
- Moderate degree of *bhrama*: 3: 2-3 times per day.
- Severe degree of *bhrama* :4: all time

#### 2) *Hriddrav* (palpitation)

- Absent :1: Normal
- Mild degree of *hrudravad* : 2:at particular activity.
- Moderate degree of *hrudravad*:3 :intermittent.
- Severe degree of *hrudravad*:4:all time

#### 3) *Nidranash* (Insomnia)

- Absent :1: Normal
- Mild degree of *nidranash*:2: Absent of deep sleeping.
- Moderate degree of *nidranash*:3: 4-6 times rising.
- Severe degree of *nidranash*:4: 6-8 times rising on night

**4) *Klama* (Exhaustion without any exertion)**

- Absent :1:Normal
- Mild degree of *klama*:2: occasionally for short duration.
- Moderate degree of *klama* :3: intermittend not affect daily routine.
- severe degree of *klama*:4:all time.

**5) *Malbaddhata*(Constipation): no :0 yes:1****B. Objective criteria-Measuring blood pressure.**

The diagnosis was based on the Blood pressure measurement and the criteria for normal, Pre hypertension, Hypertension stage1, and Hypertension stage 2 given by 7<sup>th</sup> report of Joint National committee on prevention, detection, evaluation and treatment of High Blood Pressure.<sup>[18]</sup>

**Table no 8: Assessment Criteria of Blood pressure.**

Sr No	HYPERTENSION	SYSTOLIC.B.P	DIASTOLIC.B.P
1	Normal	>120	>80
2	Pre Hypertension	120-139	80-89
3	Stage 1 Hypertension	140-159	90-99
4	Stage 2 Hypertension	≥160	≥100

**Assessment of total effect of therapy as follow**

- Unchanged = 25% relief in Symptoms of (Below) EHT.
- Encouraging response = 25 to 50% relief of in Symptoms of EHT.
- Markey improved / encouraging response:-More than 50 to 80% relief.
- Cure/ Excellent response: - 100% relief.

**Statistical Observation**

It was decided that depending on the observations and data available total six subjective criteria was studied so analysis and testing of hypothesis was done by Wilcoxon Sum test. The test was applied in the group to analysis the drug on Symptoms. And to study the comparison of both drug Man whittny test was applied between the groups.

## Observation of Wilcoxon Sum Rank test-Group A

Table No 9: Results of Wilcoxon Sum test for Group A.

Results	<i>Shirashool</i>	<i>Bhrama</i>	<i>Klama</i>	<i>Hritdrava</i>	<i>Nidranasha</i>	<i>Malabadhata</i>
W- Value	0	0	0	0	0	0
Mean Difference	1.43	1.87	1.5	1.56	1.94	1.36
Sum of pos. Ranks	630	465	253	325	561	406
Sum of neg. ranks	0	0	0	0	0	0
Z-value	-5.1594	-4.7821	-4.1069	-4.3724	-5.0119	-4.6226
Mean (W):	315	232.5	126.5	162.5	280.5	203
Standard Deviation (W):	61.05	48.62	30.8	37.17	55.97	43.91
Sample Size (N):	35	35	35	35	35	35
W-value	0	0	0	0	0	0
P-Value	< .00001	< .00001	< .00001	< .00001	< .00001	< .00001
Result	significant at p < .05	significant at p < .05	significant at p < .05	significant at p < .05	significant at p < .05	significant at p < .05

## Group B

Table No 10: Wilcoxon Sum test for Group B.

Results	<i>Shirashool</i>	<i>Bhrama</i>	<i>Klama</i>	<i>Hritdrava</i>	<i>Nidranasha</i>	<i>Malabadhata</i>
W- Value	0	6.5	0	0	0	10
Mean Difference	2.5	1.79	1.45	1.35	2.03	1.65
Sum of pos. Ranks	528	399.5	210	276	595	200
Sum of neg. ranks	0	6.5	0	0	0	10
Z-value	-4.9365	-4.4746	-3.9199	-4.1973	-5.0862	-3.5466
Mean (W):	264	203	105	138	297.5	105
Standard Deviation (W):	53.48	43.91	26.79	32.88	58.49	26.79
Sample Size (N):	35	35	35	35	35	35
W-value	0	0	0	0	0	10
P-Value	< .00001	< .00001	0.00004	< .00001	< .00001	0.00019
Result	significant at p < .05	significant at p < .05	significant at p < .05	significant at p < .05	significant at p < .05	significant at p < .05

## Mann- Whitney test

Mann- Whitney test was applied between the group to see the significance of treatment at p < 0.05.

1. *Shirashool*Table No 11: Mann- Whitney Results for *Shirashool*.

Results	Group A	Group B	Group A & B Combine
Sum of ranks	1235.5	1249.5	2485
Mean of ranks	35.3	35.7	35.5
Expected sum of ranks	1242.5	1242.5	-
Expected mean of ranks	35.5	35.5	-

U-value	619.5	605.5	605.5
Expected U-value	612.5	612.5	
Standard Deviation	-	-	85.1347
Z-Score	-	-	-0.07635

## 2. *Bhrama*

Table No 12: Mann- Whitney Results for *Bhrama*.

Results	Group A	Group B	Group A & B Combine
Sum of ranks	1137.5	1347.5	2485
Mean of ranks	32.5	38.5	35.5
Expected sum of ranks	1242.5	1242.5	-
Expected mean of ranks	35.5	35.5	-
U-value	717.5	507.5	507.5
Expected U-value	612.5	612.5	-
Standard Deviation	-	-	85.1347
Z-Score	-	-	-1.22747

## 3. *Hridrava*

Table No 13: Mann- Whitney Results for *Hridrava*.

Results	Group A	Group B	Group A & B Combine
Sum of ranks	1242.5	1242.5	2485
Mean of ranks	35.5	35.5	35.5
Expected sum of ranks	1242.5	1242.5	-
Expected mean of ranks	35.5	35.5	-
U-value	612.5	612.5	612.5
Expected U-value	612.5	612.5	-
Standard Deviation	-	-	85.1347
Z-Score	-	-	0.00587

## 4. *Nidranasha*

Table no 14: Mann- Whitney results of *Nidranasha*.

Results	Group A	Group B	Group A & B Combine
Sum of ranks	1365	1120	2485
Mean of ranks	39	32	35.5
Expected sum of ranks	1242.5	1242.5	-
Expected mean of ranks	35.5	35.5	-
U-value	490	735	<b>490</b>
Expected U-value	612.5	612.5	-
Standard Deviation	-	-	85.1347
Z-Score	-	-	1.43302



5. *Klama*Table No 15: Mann- Whitney Results for *Klama*.

Results	Group A	Group B	Group A & B Combine
Sum of ranks	1190	1438	2485
Mean of ranks	34	38.86	35.5
Expected sum of ranks	1277.5	1350.5	-
Expected mean of ranks	36.5	36.5	-
U-value	735	560	560
Expected U-value	647.5	647.5	-
Standard Deviation	-	-	88.7576
Z-Score	-	-	0.9802

6. *Malabadhata*Table No 16: Mann- Whitney results for *Malabadhata*.

Results	Group A	Group B	Group A & B Combine
Sum of ranks	1277.5	1207.5	2485
Mean of ranks	36.5	34.5	35.5
Expected sum of ranks	1242.5	1242.5	-
Expected mean of ranks	35.5	35.5	-
U-value	577.5	647.5	560
Expected U-value	612.5	612.5	-
Standard Deviation	-	-	85.1347
Z-Score	-	-	0.40524

## Blood pressure analysis

Table No 17: Percentage relief in Systolic Pressure.

Sr. No	Systolic	Group A		% of relief	Group B		% of relief
		Before Treatment	After Treatment		Before Treatment	After Treatment	
1	110	0	1	2.8%	0	1	2.8%
2	120	0	19	54.29%	0	14	40%
3	130	10	14	40%	4	18	51.43%
4	140	16	1	2.8%	18	2	5.7%
5	150	9	0	0	12	0	0
6	160	0	0	0	1	0	0
7	Total	35	35	100%	35	35	100%

Table No 18- Percentage Relief in Diastolic Pressure.

Sr.No	Diastolic	Group A		% of relief	Group B		% of relief
		Before Treatment	After Treatment		Before Treatment	After Treatment	
1	70	0	0	0	0	1	2.85%
2	80	2	30	85.72%	5	32	91.42%
3	90	9	5	14.28%	7	2	5.73%
4	100	24	0	0	23	0	0
5	Total	35	35	100%	35	35	100%

## Showing Percentage of relief in symptoms

Table No 19: Percentage relief from symptoms.

Sr No	Symptoms	Group	% relief	Remark
1	<i>Shirashool</i>	A	60%	Average Relief
2		B	60%	Average Relief
3	<i>Bhrama</i>	A	100%	Excellent Relief
4		B	85.71%	Good Relief
5	<i>Nidranash</i>	A	62.85%	Mild Relief
6		B	88.57%	Good Relief
7	<i>Hridrav</i>	A	97.14%	Excellent Relief
8		B	97.14%	Excellent Relief
9	<i>Klam</i>	A	100%	Excellent Relief
10		B	85.71	Good Relief
11	<i>Malabadhata</i>	A	77.14	Moderate Relief
12		B	60%	Average Relief

## DISCUSSION AND RESULTS

It was decided that depending on the observations and data available total six subjective criteria was studied so analysis and testing of hypothesis was done by Wilcoxon Sum test. The test was applied in the group to analyse the drug on Symptoms. And to study the comparison of both drug Man Whitney test was applied between the groups. *Haritkyadi churna* gives 60% relief in *Shirashool*, 100% relief in *Bhrama*, *Hritdrav* and *Klama*, 62.85% relief from *Nidranasha* and 77.14% relief from *Malabadhata*.

*Sarpagandha churna* gives relief 60% from *Shirashool* and *Malabadhata*, 88.57 % relief from *Bhrama*, *Klama*, and *Nidranasha* and 97.14% relief from *Hridrav*.

## CONCLUSION

*Haritkyadi churna* gives average relief i.e. 60% in *Shirashool*, Excellent relief i.e. 100% in *Bhrama*, *Hridrav* and *Klama*, Mild relief i.e. 62.85% from *Nidranasha* and Moderate relief i.e. 77.14% from *Malabadhata*. *Sarpagandha churna* gives average relief i.e. 60% from *Shirashool* and *Malabadhata*, good relief i.e. 88.57 % from *Bhrama*, *Klama*, and *Nidranasha* and excellent relief i.e. 97.14% from *Hritdrav*.

The significance of the test applied was at  $p < 0.05$  so the null hypothesis “*Haritakyadi churna* and *sarpgandha churna* when given at the dose of 5 gm after meal is not effective in the management of Essential Hypertension” was rejected and the hypothesis “*Haritakyadi churna* when given at the dose of 5gm after meal is more effective than *Sarpagandha churna* in the management of Essential hypertension” get accepted.

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