



A CLINICAL EVALUATION OF RAKTADABASHAMAK GHANA VATI IN THE MANAGEMENT OF ESSENTIAL HYPERTENSION

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ABSTRACT

In this current era of technology, industrialization and urbanization human beings have become more inclined towards unhealthy diet, sedentary lifestyle and stress which has given rise to various lifestyle related disorders of which Hypertension is of utmost significance. Considering its increasing prevalence and development of drug resistance a study related to clinical evaluation of *Raktadabashamak Ghana Vati* (a self formulated drug) consisting of Root of *Jatamansi* (*Nordostachys jatamansi*) - 1 part, Root of *Gokshura* (*Tribulus terrestris*) - 1 part, Stem Bark of *Arjuna* (*Terminalia arjuna*) - 1/2part, Whole herb of *Brahmi* (*Bacopa monnireri*) - 1 part. Root of *Vacha* (*Acorus calamus*) - 1/4 part, Root of *Tagara* (*Valeriana wallichii*) - 1/2 part, was undertaken in 20 hypertensive patients for 2 months. Results obtained with *Raktadabashamak Ghana Vati* 2 tablets twice daily after meals with luke warm water on 18 patients were 18.6% relief in Systolic Blood Pressure, 18.5% relief in Diastolic Blood Pressure, 9.3% relief in Pulse rate, 18.8% relief in Pulse pressure, 19.05% relief in Mean Arterial Pressure which were all statistically highly significant. Overall response of *Raktadabashamak Ghana vati* was excellent in 17.6% patients and marked improvement in 41.1%. These facts lead to the conclusion that *Raktadabashamak Ghana vati* can be a effective treatment for essential hypertension. Remission of treatment lead to increase in Blood pressure However, Study should be repeated by taking sample with longer duration to see whether the recurrence of disease in follow ups has decreased or not.

KEYWORDS: *Arjuna, Brahmi, Essential hypertension, Gokshura, Hypertension, Jatamansi, Raktadabashamak Ghana vati, Tagar, Vacha.*

INTRODUCTION

In this current era of technology, industrialization and urbanization, human beings have become more inclined towards unhealthy diet, sedentary lifestyle and stress which has given rise to various lifestyle related disorders of which Hypertension is of utmost significance. Hypertension or high blood pressure, sometimes called arterial hypertension, is a chronic medical condition in which the blood pressure in the arteries is elevated. Blood pressure above 140/90 mmHg is mainly considered as hypertension.

In India overall prevalence have been found 29.8% (27.6% in rural parts & 33.8% in urban parts).¹ ICMR & AIIMS study had declared India as Nation of hypertension².

Considering its high prevalence and the fact that till now there is no permanent cure for hypertension an attempt has been made in our project "clinical evaluation of *Raktadabashamak Ghana vati* in the management of essential hypertension" to find a reliable, cost effective, safe and easy to administer *Ayurvedic* medicine.

Objective

To evaluate the effect of *Raktadabashamak Ghana vati* on clinical and biochemical parameters of patient of essential hypertension.

Materials and methods

Diagnosis was mainly based on 3 readings of sphygmomanometer. Both known cases of essential

hypertension as well as newly diagnosed patients were included in the study as per classification of hypertension of 7th report of Joint National Committee(JNC)³.

Constituents of '*Raktadabashamaka Ghana Vati*' (self formulated)

1. Root of *Jatamansi* (*Nordostachys jatamansi*) – 1 part
2. Root of *Gokshura* (*Tribulus terrestris*) – 1 part
3. Stem Bark of *Arjuna* (*Terminalia arjuna*) – 1/2part
4. Whole herb of *Brahmi* (*Bacopa monnireri*) – 1 part
5. Root of *Vacha* (*Acorus calamus*) – 1/4 part
6. Root of *Tagara* (*Valeriana wallichii*) – 1/2 part

The drug was prepared by processing the *Churna* of raw drugs into *Kwatha* form (*Churna* + 8 times of water and heat upto 1/8 times remaining) which was then cooked in medium heat for conversion into *Ghana* form and then tablets were made after drying of *Ghana* part.

Inclusion criteria

- Age between 20 to 70 years.
- Blood pressure – Systolic blood pressure – 140-179 mmHg.
Diastolic blood pressure -90-109mmHg

Exclusion criteria

- Patients having hypertension due to other secondary disease like renal disease, endocrinal disorder, Neurogenic causes, etc.
- Patients having complication of hypertension.

➤ Any other serious medical & surgically ill patients.

Investigations

Investigations were carried out to rule out secondary hypertension or any other pathologic condition. Hb%, TLC, DLC, ESR, BSL-F & PP, lipid profile, Blood urea, S.creatinine, urine R & M and ECG.

Dose of Drug

2 tablets of *Raktadabashamak Ghana vati* (each tablet of 250 mg) were given orally twice daily after meal with luke warm water.

Duration: Duration of clinical trial was of two months. Clinical assessment was done at 15 days interval.

Pathya and Apathya (Do's and Don't's)

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.

Criteria for assessment

A. Objective criteria : changes in blood pressure, pulse pressure, pulse rate and mean arterial pressure.

B. Subjective criteria : changes in symptoms *Shiroruja* (headache), *Hridrava* (palpitation), *Bhrama* (vertigo), *Klama* (fatigue), *Akshiraga* (Redness in eye), *Krodhprachurya* (Irritability), *Anidra* (insomnia). All the symptoms were given suitable score.

0	Normal
1	Mild
2	Moderate
3	Severe
4	Very severe

The total effect of therapy was assessed by percentage of score reduction.

Assessment score: percentage relief in signs and symptoms as follows:

- Excellent response >75%
- Marked response 50 to 75%
- Mild response 25-50%
- No response <25%

Statistical analysis: Paired t test, was carried at the level of 0.05, 0.01, 0.001 of p level⁴. Thus the obtained results were interpreted as:

P> 0.05 Not Significant

P< 0.01 & <0.05 significant

P< 0.001 highly significant

OBSERVATIONS

In present research work, out of 20 registered patients 18 patients discontinued the treatment. 18

Table 1: Effect of Raktadabashamak Ghana Vati in essential Hypertension

Parameters	Mean Score ± S.D					% relief	't'	P
	BT	A ₁	A ₂	A ₃	A ₄ (AT)			
SBP	153.7±12.77	133.7±12.1	131.±12.1	129.5±12.6	124.94±14.6	18.6	9.3	<0.001 H.S
DBP	103.76±7.8	76.35±6.2	90.82±10.2	87.05±12.7	84.4±12.88	18.5	6.9	<0.001 H.S
Pulse Rate/min	82.7±4.64	79.9±3.29	76±3.80	76.5±4.72	75±6.07	9.3	5.84	<0.001 H.S
Pulse pressure	49.88±8.9	43.64±13.3	41.1±7.4	42.2±6.8	40.4±6.9	18.8	6.26	<0.001 H.S
MAP	120.39±8.7	104.5±12.3	104.4±10	101.1±12.2	97.4±12.3	19.05	7.65	<0.001 H.S

patients completed the trial. Maximum number of patients were belonging to age group 51-60 years(23.3%) followed by age group 41-50 years(21.7%).majority of the patients were females(53.3%).61.7% of patients were residents of urban areas. majority of patients were of *Vata-Pittaja prakriti*(Physical constitution) (45%) and 46.7% were of lower middle class. lifestyle of 75% patients were sedentary and 35% patients had addiction of smoking. symptoms recorded in the patients were headache (12 patients), vertigo (7 patients), palpitation (10 patients), fatigue (12 patients), insomnia (11 patients), Irritability (11 patients), Redness of eyes (11 patients).

RESULTS

Effect on Blood pressure: the mean systolic blood pressure before treatment was 153.7 mmHg which dropped by 18.6% to 124.94mmHg after 60 days. statistically this reduction in systolic blood pressure after 2 months was highly significant (Table -1).

Similarly initial mean diastolic blood pressure was 103.76 mmHg before treatment which reduced to 84.4mmHg(18.5%) after 60 days. Statistically this reduction was also highly significant.(Table-1).

Effect on pulse rate : mean pulse rate was 82.7/minute which reduced to 75/minute after completion of treatment. Overall percentage relief was 9.3% which was highly significant. (Table-1).

Effect on Pulse pressure : mean pulse pressure before treatment was 49.88mmHg before treatment which got reduced to 40.4mmHg after completion of trial giving a highly significant percentage relief of 18.8%.(Table-1).

Effect on mean arterial pressure: the mean arterial blood pressure before treatment was 120.39mmHg which dropped to 97.4mmHg after 60 days. Percentage relief was 19.05% which was highly significant. (Table-1).

Effect on the symptoms: 83.78% relief in Headache which was statistically highly significant, . Irritability was relieved by 75.8% which was also highly significant. Vertigo was relieved by 82.3% which was statistically highly significant. Insomnia was relieved by 80.7% which was also statistically highly significant. Palpitation was relieved by 70.8%, Fatigue was relieved by 64.5% which was statistically significant. Redness in eye was relieved by 57.6% which was statistically significant. (Table-2).

Overall effect of therapy: Assessment of overall effects of the drug was done based upon relief in blood pressure and the symptoms after 60 days of treatment. It was found out that 17.6% of patients showed excellent response and 41.1% patient showed marked response. (Table-3).

Dose related side effects: no side effects were observed in any patient during the study.

Table 2: Effect of therapy on symptoms

Symptoms	Mean Score \pm S.D					% relief	't'	P
	BT	A ₁	A ₂	A ₃	A ₄ (AT)			
<i>Shiroruja</i> (Headache)	2.11 \pm 1.6	1.4 \pm 0.97	0.88 \pm 1.1	0.35 \pm 1.38	0.7 \pm 1.2	83.78	5.44	<0.001 HS
<i>Hrid drava</i> (Palpitation)	1.61 \pm 1.50	0.94 \pm 0.70	0.74 \pm 1.08	0.69 \pm 1.11	0.47 \pm 1.37	70.8	3.85	<0.01
<i>Klama</i> (Fatigue)	1.72 \pm 1.31	1.27 \pm 0.51	1.11 \pm 0.60	0.78 \pm 0.93	0.61 \pm 1.0	64.5	3.73	<0.01
<i>Bhrama</i> (Giddiness)	0.94 \pm 1.36	0.61 \pm 0.48	0.39 \pm 0.85	0.4 \pm 0.85	0.17 \pm 1.16	82.3	4.83	<0.001 HS
<i>Akshiraga</i> (redness of eyes)	1.55 \pm 1.46	1.27 \pm 0.46	0.72 \pm 1.15	0.55 \pm 1.08	0.67 \pm 1.05	57.6	3.91	<0.01
<i>Krodhaprachurya</i> (Irritability)	1.70 \pm 1.5	1.11 \pm 0.87	0.94 \pm 0.97	0.76 \pm 1.19	0.41 \pm 1.19	75.8	4.06	<0.001 HS
<i>Alpanidra</i> (Reduced sleep)	1.3 \pm 1.52	0.9 \pm 0.77	0.6 \pm 1.08	0.4 \pm 1.29	0.2 \pm 1.37	80.7	4.63	<0.001 HS

Table 3: Overall effect of drug therapy with *Raktadabashamak Ghana vati*

Overall effect of therapy	No. of cases	Percentage
Excellent response	3	17.6%
Marked response	7	41.1%
Mild response	5	29.4%

DISCUSSION

- 60 days treatment of *Raktadabashamak Ghana Vati* significantly reduced systolic and diastolic blood pressure within normal limits. SBP was reduced by 18.6% from 153.7mmHg to 124.9mmHg. DBP was reduced by 18.5% from 103.7 to 84.4mmHg.
- The therapy significantly reduced mean pulse pressure by 18.8% from 49.8mmHg to 40.4mmHg and mean arterial pressure by 19.05% from 120.3mmHg to 97.4mmHg.
- The therapy also significantly reduced pulse rate within normal limits from 82.7/min to 75/min.
- The therapy produced highly significant result in headache and insomnia, significant result in palpitation, fatigue, Redness in eyes, Irritability and Vertigo.
- Hence it can be concluded that *Raktadabashamak Ghana vati* brought significant changes in blood pressure and symptoms associated with essential hypertension and brought blood pressure to normal limits.
- Jatamansi is medhya* (brain tonic) and *Vaatnadishamak* (sympatholytic) due to these actions it relaxes brain and nervous system and causes vasodilation. its chemical constituent Jatamansone is useful in cardiac arrhythmias⁵. Various clinical studies have shown its antihypertensive effect.⁶
- Gokshur* is well known for its *Mutral* (diuretic effect) apart from this it also used in *Hridrogas* (cardiovascular disorders) in Ayurveda⁷. Clinical studies have shown its antihypertensive, antidepressant and anxiolytic activities⁸.
- Arjuna* has been said as *Hridya* (cardio tonic) in Ayurvedic texts. It provides strength to cardiac muscles and stroke volume which in turn decreases heart rate⁹. the flavonoids components present in the bark of *Arjuna* tree have antioxidant properties¹⁰, so *Arjuna* bark powder is beneficial in ischemic heart diseases associated with oxidative stress. Studies have proven its cardio protective effects. It also shows anticoagulant property which can be used in coronary artery diseases and thus can reduce hypertension of cardiac origin.¹¹
- Brahmi* in Ayurvedic medicine system is used as a powerful *Medhya* (brain tonic) drug as well as a memory enhancer. It is *Balya* (provides strength) to *Vaatnadisansthan* (nervine tonic).¹² *Brahmi* extract bacosides have shown anxiolytic, antidepressant, antistress and antioxidant activity.¹³
- Vacha* is also used as *Medhya* drug in Ayurvedic medicine moreover, due to its *Tikshna guna* (sharp) it has a *Lekhaniya* action which is beneficial in high lipid profile. Studies have shown its blood pressure lowering and vascular modulator effects.¹⁴
- Tagara* is mainly used in Ayurvedic medicine to treat nervousness, insomnia and heart palpitations, *Shiro rogas* (headaches) and *Rakta vikaras* (blood disorders). valerenic acid present in the herb has been shown to inhibit the breakdown of neurotransmitter GABA which results in sedation. Studies have also shown its antihypertensive, anxiolytic effect.¹⁵
- Since essential hypertension is a multi factorial disease, treatment modalities should be based upon vitiated *Vata dosha* along with *Pitta* and *Kapha*. The drug formulations should have properties like *Medhya* (Nootropic), *Hridya* (Cardiotonic), *Mutrala* (Diuretic), *Vatanadishamak* (Nervine sedative), *Manasadoshahara* (Anti anxiety), *Deepana* and *Pachana* (Increase metabolic rate).
- Overall effect of *Raktadabashamak Ghana Vati* can be summarized as *Tridoshashamaka* (mainly *Vata*), *Manasadoshahara*, *Vatanadishamaka*, *Hridya*, *Medhya*, *lekhaniya* and *mutrala*. Due to wider range of action, *Raktadabashamak Ghana Vati* was more successful in reducing Blood pressure.
- Remission of treatment lead to increase in Blood pressure, which leads to fact that essential hypertension is a *Yapya* (Difficult to cure)disease.

CONCLUSION

Raktadabashamak Ghana Vati 2 tablets twice daily after meals with luke warm water on 18 patients were 18.6% relief in Systolic Blood Pressure, 18.5% relief in Diastolic Blood Pressure, 9.3% relief in Pulse rate, 18.8% relief in Pulse pressure, 19.05% relief in Mean Arterial Pressure which were all statistically highly significant. Overall response of *Raktadabashamak Ghana vati* was excellent in 17.6% patients and marked improvement in 41.1%. These facts lead to the conclusion that *Raktadabashamak Ghana vati* can be a effective treatment for essential hypertension. Remission of treatment lead to increase in Blood pressure.

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