A Comparative Clinical Evaluation of Raktadabashamak Ghana Vati and Sarpagandha Ghana Vati in the Management of Essential Hypertension

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Abstract

Hypertension is one of the major causes of disability and death all over the world. Considering its increasing prevalence and development of drug resistance a clinical study entitled **"A comparative clinical evaluation of *Raktadabashamak Ghana Vati* and *Sarpagandha Ghana Vati* in the management of Essential Hypertension"** was undertaken in 60 hypertensive patients for 2 months. On administration of 2 tablets of Sarpagandha Ghana vati (250 mg each) twice daily after meals with luke warm water in 20 patients, mean % relief in Systolic Blood Pressure was 11.3%, Diastolic Blood Pressure was reduced by 10.7%, Pulse rate was reduced by 17.01%, Pulse pressure was reduced by 8.9%, Mean arterial Pressure was reduced by 12.09% which were all statistically highly significant. Results obtained with Raktadabashamak Ghana Vati (250 mg each)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% Patients, it was better than overall response of Sarpagandha Ghana Vati which showed only mild improvement in maximum (80%) patients. 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.

Type of study: - Comparative clinical study

Keywords: *Hypertension, Essential Hypertension, Vyana Bala Vaishamya, Sarpagandha, Ghana Vati, Raktadabashamak Ghana Vati*

Introduction

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 part [1] ICMR & AIIMS study had declared India as Nation of hypertension [2].

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 "A comparative clinical evaluation of *Raktadabashamak Ghana Vati* and *Sarpagandha Ghana Vati* in the management of Essential Hypertension" to find a reliable ,cost effective, safe and easy to administer *Ayurvedic* medicine.

Objective

To compare the effect of *Raktadabashamak Ghana vati* and *Sarpagandha Ghana vati* and to see any augmented effect when *Sarpagandha Ghana vati* is given along with *Raktadabashamak Ghana vati*.

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 'Sarpagandha Ghana Vati' (Sidhha Yoga Sangraha) [4]

1. Root of Sarpagandha (*Rauwolfia serpentina)* – 10 parts
2. Parsika Yavani seeds (*Hyoscyamus niger*) – 2 parts
3. Root of Jatamansi (*Nordostachys jatamansi)* – 1 part
4. Shuddha Bhanga leaves (*Cannabis sativa)* – 1 part
5. Root of Pippali (*Piper longum*) – 1/8 part

Constituents of '*Raktadabashamaka Ghana Vati* [5] (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 *Bhrahmi* (*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 raw drugs into *kwatha* form (kwath churna + 8 times of water→heat⟶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 diease, endocrinal disorder, Neurogenic causes, etc.
- Patients having complication of hypertension.
- Any other serious medical & surgically ill patients

Investigations

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

Table 1: Drug Trial Schedule

GROUP	NO.OF PTS	DRUG	DOSE	DURATION
A	20	*Sarpagandha Ghana vati* (Each tablet weighted 250 mg)	2 tab X B.D	60 Days
B	20	*Raktadabashamak Ghana vati* (Each tablet weighted 250 mg)	2 tab X B.D	60 Days
C	20	*Sarpagandha Ghana vati* and *Raktadabashamak Ghana vati*	2 tab(1 tab each) X B.D	60 Days

Anupana – 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.

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%6

Statistical analysis: Paired t test, was carried at the level of 0.05, 0.01, 0.001 of p level[4]. Thus the obtained results were interpreted as:

P> 0.05 Not Significant

P< 0.01 & <0.05 significant

P< 0.001 highly significant

Results

While observing subjective and objective assessment following results are found:

GROUP A

In objective assessment of Group A (*Sarpagandha Ghana vati*) the mean score of systolic Blood pressure was found 148.7 mmHg before treatment which got reduced to 136.5 mmHg after treatment which statically showed highly significant result($p<0.001$), mean score of Diastolic blood Pressure before treatment was 98 mmHg which reduced to 83.1mmHg after treatment Mean pulse rate before treatment was 83.6/min which reduced to 69/min, Pulse pressure before treatment was 50.7 mmHg which reduced to 46.7 mmHg after treatment, Mean arterial Pressure before treatment was 114.9 which got reduced to 101.1 mmHg after treatment. These all results were statistically highly significant ($p<0.001$).

GROUP B

In objective assessment of Group B *(Raktadabashamak Ghana vati*) the mean score of systolic Blood pressure was found 153.7 mmHg before treatment which got reduced to 124.94 mmHg after treatment, mean score of Diastolic Blood Pressure before treatment was 103.8 mmHg which reduced to 84.4 mmHg after treatment. Mean pulse rate before treatment was 82.7/min which reduced to 75/min, Pulse pressure before treatment was 49.9 mmHg which reduced to 40.4 mmHg after treatment, Mean arterial Pressure before treatment was 120.4mmHg which got reduced to 97.4mmHg after treatment. These all results were statistically highly significant ($p<0.001$).

GROUP C

In objective assessment of Group C the mean score of systolic Blood pressure was found 150.2 mmHg before treatment which got reduced to 128.11 mmHg after treatment, mean score of Diastolic blood Pressure before treatment was 95.55 mmHg which reduced to 82.5 mmHg after treatment Mean pulse rate before treatment was 86.9/min which reduced to 73.7min,Pulse pressure before treatment was 54.6 mmHg which reduced to 46.11 mmHg after treatment, Mean arterial Pressure before treatment was 113.7 which got reduced to 97.5mmHg after treatment. These all results were statistically highly significant ($p<0.001$).

Follow up study

Out of 55 patients 43 patients came for follow up, 25 patients were reported to have increase in their Blood pressure.20 patients complained of recurrence of symptoms after completion of trial. This gives a clear idea about the Yapya nature of the disease.

Comparison of the effects

When percentage of relief was compared on parameters, Group B showed maximum improvement in systolic Blood Pressure (18.6%), Diastolic Blood Pressure (18.5%), Pulse pressure (18.8%) and Mean arterial pressure (19.05%). Group A showed maximum relief in pulse rate (17.01%).

Overall effect of therapy

Overall response in Group A was mild improvement in 80% patients and marked improvement in 5% patients, while Group C showed Mild improvement in 61.6% patients and marked improvement in 27.8% patients, Group B showed marked improvement in 41.1% patients and excellent response in 17.6% patients. Thus we can conclude that *Raktadabashamak Ghana Vati* prescribed in Group B showed better results than both Group A (Sarpagandha Ghana vati) and Group C (*Raktadabashamak Ghana vati given along with Raktadabashamak*

Ghana vati)

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

Table 2: Overall effect of drug therapy

STATUS	Group A(n=20)		Group B(n=18)		Group C(n=17)	
	No.	%	No.	%	No.	%
Excellent (≥75%)	0	0	3	17.6%	1	5.5%
Marked improvement (50-74%)	1	5%	7	**41.1%**	5	27.8%
Mild improvement (25- 49%)	16	**80%**	5	29.4%	11	**61.1%**
No improvement (≤24%)	3	15%	2	11.8%	1	5.5%

Discussion

The first trial drug "*Sarpagandha Ghana Vati*" described by *Vaidya Yadavji Trikamji* in *Sidhha Yoga Sangraha* is a herbal preparation. This Drug is being manufactured by various pharmaceutical companies and has documented Antihypertensive effect. The constituents are *Sarpagandha, Parasika yavani, Jatamansi, Bhanga, Pippali mula*.

Sarpagandha has been extensively studied in various researches. It is *Katu vipaka, Ushna Virya with Nidrajanana Prabhava*, by which it corrects *Vata* and *Kapha dosha* [6]. It is *Hridaya avasadaka* by which it lowers cardiac output [7]. Previous studies have already proved its Antihypertensive activity [8].

Though its alkaloid Reserpine has been studied to produce mental depression, suicidal tendency, nasal stuffiness, diarrhoea and abdominal cramps, none of the mentioned side effect was observed in our study, however, clinical trials with longer duration are required to establish this fact.

The second constituent is "*Parasika Yavani"* which contains *Tikta, Katu Rasa, Katu vipaka* and *Ushna Virya.* By virtue of its properties it has a *Kapha vata* shamak, Hridayaavasadaka, *Nidrajanana* effect [9]. It also has *pachaka [10].* (Visheshat Pachni) effect by which it corrects *Ama* formation which is responsible for *Rasa Rakta dushti* .Its dried leaf powder contains natural anticholinergic alkaloid Hyoscine which produces Central effects (depressant) at low doses, Therefore can be used in stages of anxiety or other mental stress conditions which are important triggering factors in inducing essential Hypertension.

The third constituent is "*Jatamansi*" It contains *Tikta, Kashaya* and *Madhura Rasa, Katu vipaka* and *Shita Virya*, It also has *Manasadoshahara Prabhava.* By virtue of its properties it exhibits *Tridoshahara Prabhava [11]*. Essential hypertension is also considered as *Tridoshaja vyadhi*. It also has *Hridaya niyamaka* effect through which it corrects cardiac output. Its *Manasadoshahara Prabhava* produces *Shamaka effect* on *Manasika dosha Raja* and *Tama* which also play important role in *Samprapti* of Essential Hypertension. Various clinical studies have proven its encouraging results in hypertensive states and cardiac conditions like cardiac arrhythmias, functional cardioneurosis [12].

The fourth constituent is "*Bhanga*" which contains *Tikta Rasa, Katu vipaka* and *Ushna Virya* pharmacological properties. It is *Kapha Vata shamaka*, *Nidrajanaka*, *Akshepahara* and potent *Deepana, Pachana [13]*. Its anti-anxiety effects are even mentioned in *Atharvaveda* (Ath.8/7/20)

The fifth constituent is "*pippalimula*", It contains *Katu rasa, Madhura vipaka* and *Ushna Virya*. It pacifies vitiated *Vata* and *Kapha*, and also acts as *Daha Prashamana* and potent *vataanulomaka [14].* According to Acharya Charaka *Pippali mula* is specially *Deepaniya Pachniya [15],* therefore its probable mode of action may be on correction of *Agni* .It normalizes *Dhatus* by digestion of *Ama*. Previously anti-inflammatory action of *Pippali* has been studied [16]. This property may also help in hypertension induced oxidative stress and inflammation in endothelium of arteries. Its chemical constituent 'Piperine' has also been studied as bioavailability enhancer. Therefore addition of Pippali mula in *Sarpagandha Ghana vati* may also have helped in improving absorption and bioavailability of drug.

As a whole the combined action of "*Sarpagandha Ghana vati*" can be summarised as *Vata pradhana Tridoshashamak*, It pacifies *Manasika Dosha* and promotes digestion of *Ama*. These actions result in *Samprapti vighatana* of essential Hypertension and therefore reduce

Blood pressure.

The second trial Drug is "*Raktadabashamak Ghana Vati*". It is also a herbal preparation containing a combination of all time tested drugs. All the drugs have been described in Ayurvedic texts and have been studied extensively in various research works also there was no known serious adverse effect of any of the drugs; therefore these drugs were taken in our study.

The first constituent is *Jatamansi* which is *Tridoshashamaka, Medhya* and *Vatanadishamak* due to these actions it relaxes brain and nervous system and causes vasodilatation. The second constituent *Gokshura* which is *Vatakaphashamaka* [17] .It is well known for its *mutrala* [18] effect, through this it may help in reducing the fluid volume overload from body which is also an important factor responsible for high blood pressure, apart from this it is also used in *Hridrogas* in Ayurveda. Clinical studies have shown its antihypertensive, antidepressant and anxiolytic activities [19].

The third constituent is *Arjuna* is *Kaphapittashamaka, Arjuna* has been said as *Hridya* in Ayurvedic texts. It provides strength to cardiac muscles and increases stroke volume which in turn decreases heart rate [20] .The flavonoids components present in the bark of *Arjuna* tree have antioxidant properties (Shreya, 2013), Studies have proven its cardio Protective effects. It also shows vasodilator and Hypolipidemic effects [21], through this it can protect from atherosclerosis.

The fourth constituent, *Brahmi* in Ayurvedic medicine system is used as a powerful medhya drug. It is *balya* to vaatnadisansthan. *Brahmi* extract bacosides have shown anxiolytic, antidepressant, antistress and antioxidant activity [22].

The fifth constituent *Vacha* is used as *medhya* drug in Ayurvedic medicine, due to its *Tikshna guna it* has a *lekhaniya* [23] action, by virtue of this property it can remove *Dhamani uplepa* and thereby clearing *Vayu margaavarodha*. According to previous clinical study it possess vasodilatory property through which it can lower Blood pressure by reducing peripheral resistance [24].

Tagara is mainly used in *Ayurvedic* medicine to treat nervousness, insomnia and heart palpitations, *shiro rogas* and *rakta vikaras* .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 [25].

Overall effect of *Raktadabashamak Ghana Vati* can be summarized as *Tridoshashamak* (mainly vata), *Manasadoshahara, vatanadishamaka, Hridya, medhya, lekhaniya* and *mutrala*.

The drug constituents of *Raktadabashamak Ghana vati* works on all possible mechanisms responsible for causing essential hypertension. Its multifactorial action may be the possible reason for its better effect than *Sarpagandha Ghana vati.*

Conclusion

- Essential hypertension can be correlated as *Vata pradhana Tridoshaja vyadhi.*
- Contrary to previous belief that its increased incidence is found in elderly patients it has been studied that it is also significantly prevalent in middle aged persons.
- High intake of salt and tea, sedentary lifestyle, Lack of exercise precipitate the disease.
- Stress is most powerful factor for causing essential Hypertension.
- 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, Hridya, Mutrala, Vatanadishamak, Manasadoshahara*, *Deepana and Pachana*
- Overall effect of *Raktadabashamak Ghana Vati* can be summarized as *Tridoshashamaka* (mainly *vata*), *Manasadoshahara, Vatanadishamaka, Hridya, Medhya, lekhaniya and mutrala*. Overall effect of *Sarpagandha Ghana Vati* was *Tridoshashamak* and *Manasadoshahara* and *Nidrajanaka.*
- Due to wider range of action, *Raktadabashamak Ghana Vati* was more successful in reducing Blood pressure than *Sarpagandha Ghana vati.*
- Remission of treatment lead to increase in Blood pressure, which leads to fact that essential hypertension is a *Yapya* disease

Conflict Of Interest

The author/s declare/s that there is no conflict of interest regarding the publication of this manuscript

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