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A Clinical Study on the Effect of Ashwagandhadi Churna in the management of Rakta-Gata-Vata with special reference to Essential Hypertension

Dr. Aitilin K. Kylliang¹, Dr. Shripathi Acharya², Dr. Veeraj Hegde³

¹Post Graduate Scholar, ²Professor & H.O.D, ³Assistant Professor, Dept. of Kayachikitsa. Muniyal Institute of Ayurveda Medical Sciences and Hospital, Manipal, Karnataka, INDIA.

ABSTRACT

Introduction: Hypertension is an important public health challenge worldwide and remains as major cause of morbidity and mortality. Hypertension is the third most important attributable risk factor for burden of disease in South Asia (2010). In India, Hypertension is the leading cause of premature death. Hypertension is directly responsible for 29% of all stroke and 24% of heart attack in India. Objectives: To Evaluate the effect of Ashwagandhadi Churna in the management of Rakta-Gata-Vata (Essential hypertension). Materials and Methods: 40 clinically diagnosed patients of Essential Hypertension were selected based on inclusion criteria. Selected patients were randomly divided into two groups: Group A (Trial) was given Ashwagandhadi Churna in a dose of 3gms twice daily and Group B was given Sarpagandha Churna in a dose of 1gms twice daily with water for 21 days. The data was graded based on assessment criteria and was analysed statistically. Results: Outcome of the treatment after 21 days was statistically significant in most of the sign and symptom score of various subjective and objective parameters. Overall it shows statistically significant result. Discussion: The total mean of SBP, DBP, PP and MAP before treatment was 160.10, 91.4, 65.30, 114.25 respectively after 21 days of therapy the total mean of SDP, DBP, MAP, and PP are 134.60, 82.60, 51.00, 98.75 respectively and all showed statistically significant at 0.01 except DBP which showed statistically insignificant. The mean of total cholesterol, triglycerides, low density lipoproteins and High density lipoproteins before treatments are 199.85, 132.05, 116.25, and 44.90 after 21 days of therapy the total mean of total cholesterol, triglycerides, low density lipoproteins and High density lipoproteins are 189.60, 124.60, 109.25, 49.10 respectively and showing statistically significant at 0.01. Ashwagandhadi Churna is found to be effective in mild and moderate HTN and also on reducing cholesterol level (T.cho, TGL, and LDL) and slightly increases HDL level.

Key words: Essential Hypertension, Rakta-gata-vata, Sarpagandha Churna, Ashwagandhadi Churna.

INTRODUCTION

Hypertension is an important public health challenge Worldwide and remains as major cause of morbidity and mortality. Hypertension is the third most important attributable risk factor for burden of

Address for correspondence:

Dr. Aitilin K. Kylliang

Post Graduate Scholar, Dept. of Kayachikitsa, Muniyal Institute of Ayurveda Medical Sciences and Hospital, Manipal, Karnataka, INDIA

E-mail: aitilinkharkylliang@gmail.com

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disease in South Asia (2010).^[1] In India, Hypertension is the leading cause of premature death. Hypertension is directly responsible for 29% of all stroke and 24% of heart attack in India.[2] A large nationwide study (ICMR-INDIAB study) by Bhansali et al. reported Indian, 26.3% among Indian population are suffering from hypertension suffering from hypertension. [3-4] Hypertension is a silent killer as very rarely any symptom can be seen in its early stages until a severe medical complication takes place like heart attack, stroke, etc. It is most common risk factor for stroke, myocardial infarction, heart failure, peripheral vascular disease, end stage Kidney diseases etc.

In more than 95% of cases, specific underlying cause cannot be found, such patients are said to have Essential Hypertension. [5] The pathogenesis is not clearly understood, many factors may contribute to its

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development including peripheral resistance, endothelial dysfunction, Autonomic tone, renal dysfunction, neuro-humoral factor.

According to Ayurveda, the direct correlation for Hypertension is not mentioned it can be understood by assessing the involved *Doshas*, *Dooshyas*, *Srotases* and *Sthanas* etc. and it can be correlated to *Raktagata Vata*. ^[6] In *Raktagatavata*, *Raktadhatu* get vitiated by *Vatadosha* leading to *Shoshana* of *Raktadhatu* and it is unable to carry out its normal function. ^[7] Symptoms like *Tivraruja*, *Santapa*, *Aruchi*, *Bhrama*, *Klama*, *Krishata*, *Saraga*, *Shirashula*, etc. can be seen in *Raktagatavata*. ^[8-11]

Acharya Charaka has given a guideline to understand a new clinical entity not described by him in the Samhita. If a physician is unable to diagnose the disease, he should asses it's Prakruti, Samuthan and Adhishtana etc. and design a treatment protocol for such disease. The study is designed to evaluate the efficacy of Ashwagandhadi Churna in the management of Raktagata Vata (Essential Hypertension).

AIM AND OBJECTIVE

- 1. To evaluates the efficacy of *Ashwagandhadi Churna* on essential hypertension.
- 2. To find an effective safe treatment modality for hypertension and prevent the end organ damage.

MATERIALS AND METHODS

Plan of Study

Duration of study: 21 Days

Type of Study: Single Blind

Type of Sampling: Randomized

Selection of Patients

Patients who fulfilled the inclusion criteria were randomly selected from OPD and IPD of Muniyal Institute of Ayurveda Medical Sciences and Hospital, Manipal and also from referral sources and special camps were conducted for the purpose. 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).

Physical examination on the basis of Ayurveda and modern parameters was conducted for all the patients. Patients consent was taken and were examined thoroughly and the data was recorded systematically. A special research Performa was designed and duly filled for each patient.

Diagnostic Criteria

Objective and subjective parameters were utilized for diagnostic purpose.

Objective parameter

Systemic blood pressure is measured by Sphygmomanometer methods. For diagnostic purpose blood pressure of the patients was measured three times over a period of at least 3 minutes and the lowest reading recorded. Patients having blood pressure of SBP >140 mm of Hg and < 169 mm of Hg DBP >85 mm of Hg and <100 mm of Hg 140/90 mm of Hg or above were diagnosed as hypertensive and were selected for study.

Subjective parameter

- Shiroruk (Headache)
- Bhrama (Giddiness)
- Klama (Tireness)
- Anidra (Insomnia)
- Kroda Prachurata (Anger)
- Tivrashula (Severe ischemic pain)

Inclusion criteria

- Age between 30 to 70 years.
- Either sex, irrespective of religion, caste.
- Blood pressure Systolic blood pressure 140-169 mmHg and Diastolic blood pressure 90-99mmHg.

Exclusion criteria

 Patients having hypertension due to other secondary disease like renal disease, endocrinal Disorder, Neurogenic causes, etc.

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- Cerebrovascular disease (Coronary Heart Diseases, Left Ventricular Hypertrophy and Failure)
- Malignant Hypertension, Patients having complication of hypertension.

Criteria for Withdrawal

- If there is aggravation of complaint
- Personal matters
- Medical advice

Selection of Drug

Ashwagandhadi Churna is selected for the present study. Ashwagandhadi Churna contains Ashwagandha, Trikatu (Shunthi, Pipalli, Maricha), Ela, Vidanga and Nagkeshara. Research has been done on the effective of Ashwagandha root Powder in treatment of mild and moderate HTN. In national health portal they have mentioned the used of single Ashwagandha root powder for treatment of high blood pressure. Ashwagandhadi Churna is mentioned in Sahasrayoga in Churna for the treatment of Vata Roga.

Constituents of Ashwagandhadi Churna

Ashwagandha (Whithania somnifera)	Root	64 part
Shunthi (Zingiber officinale)	Rhizome	32 part
Pippali (Piper longum)	Fruit	16 part
Maricha (Piper nigrum)	Fruit	8 part
Ela (Elletaria cardamum)	Seed	4 part
Vidanga (Emblica ribes)	Seed	2 part
Nagkeshara (Messua ferrua)	Flower	1part
Sharkara		127 part

The drug was prepared by processing the grinding of raw drugs into *Churna*.

Grouping of patients

A minimum of 40 patients who fulfilled the diagnostic and inclusion criteria irrespective of their gender, caste, religion, education status and socio-economic status were taken for the study. Registered patients were allotted randomly by lottery method into two equal groups of minimum 20 patients in each as Group A and B. In Group A: were given with Ashwagandhadi Churna 3 gm twice daily after food. In Group B: were given with Sarpagandha Churna 1gm twice daily after food. Treatment duration: 21days, Anupana: Water.

The Regimen to be followed along with medicine

Ahara: Diets rich in fruits, vegetables, fat-free or low-fat milk and milk products, whole grains, fish, poultry, beans, seeds and nuts. It also contains less sodium; sweets, added sugars and beverages containing sugar; fats. Also lower in saturated fat, Trans fat and cholesterol and rich in nutrients that are associated with lowering blood pressure mainly potassium, magnesium, calcium, protein and fibres.

Investigations

- Lipid profile: S. Cholesterol, TG, LDL, HDL, and VLDL were done before and after the treatment.
- Other investigation was carried out, to rule out secondary hypertension or any other pathologic condition

Follow up Study

After completion of therapy patients were advice to report once a week for 15 days.

Assessment criteria for Overall Effect of Therapy

The data were analyzed in the following sequence;

- General observation
- Results of treatment on basis of signs and symptoms, Blood pressure reading and Biochemical parameters.

Statistical Analysis

The obtained information was analyzed statistically in terms of Mean Score (x), Standard Deviation (S.D.)

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and Standard Error (S.E.). Paired 't' test and Unpaired 't' test was carried out at the level of 0.05, 0.01 and 0.001 of P levels.

The results were interpreted as:

- P<0.05 Improvement
- P<0.01 Significant improvement
- P<0.001 Highly significant improvement

Criteria of Assessment of Result

- Controlled Relief: 100% relief in complaints
- Marked Relief: >75% relief in complaints
- Moderate Relief: 50 -74% relief in complaints
- Mild Relief: 25 49 % relief in complaints
- No Relief: 0- 25 % relief in complaints

RESULT

In present research work, Maximum number of patients were belonging to *Madhyama Vayas* i.e. 41-60 years (80.5%), Majority of the patients were males (55%) and *Vata-Pittaja Prakriti* (Physical constitution) (72.5 %) and 82.5% were of middle class. Lifestyle of 47.5 % patients was sedentary and 12.5% patients had addiction of smoking and alcohol. Symptoms recorded in the patients were *Shiroruka* (67.5%), *Anidra* (62.5%), *Bhrama* (70%), *Klama* (75%), *Krodhaprachurata* (60%).

Effect of therapy on group-A (Ashwagandhadi Churna)

Effect on blood pressure: Systolic Blood Pressure: The mean score of SBP prior to treatment was 160.10, which was reduced to 134.60, giving 16.50 % relief. This result was statistically significant at p=0.001.

Diastolic Blood Pressure: The mean score of DBP prior to treatment was 91.40, which was reduced to 82.60, giving 9.902% relief. This result was statistically insignificant as p=0.132. Effect on Pulse Pressure: The mean score of PP prior to treatment was 65.30, which was reduced to 51.00, giving 22.49 % relief. This result was statistically significant at p<0.05. Mean Arterial Pressure: The mean score of M.A.P prior to treatment was 114.25, which was reduced to 98.75, giving 14.09

% relief. This result was statistically significant at p<0.05.

Effect on sign and symptom: *Shiroruk (Headache):* The mean score of Shiroruka prior to treatment was 1.90, which was reduced to 0.70, giving 63.157% relief. This result was statistically significant at p<0.001. Bhrama (Giddiness): The mean score of Bhrama prior to treatment was 1.35, which was reduced to 0.50, giving 62.96% relief. This result was statistically highly significant at p<0. 001. Klama (fatigue): The mean score of *Klama* prior to treatment was 1.65, which was reduced to 0.40, giving 84.84% relief. This result was statistically highly significant at p<0.001. Anidra (Insomnia): The mean score of Anidra prior to treatment was 1.50, which was reduced to 0.60, giving 63.33% relief. This result was statistically significant at p<0.001. Krodhaswabhava: The mean score of Krodhaswabhava (irritability) prior to treatment was 1.10, which was reduced to 0.40, giving 63.63% relief. This result was statistically significant at p<0.001.

Effect on cholesterol: Total Cholesterol: The mean score of T. Cholesterol prior to treatment was 199.85 which were reduced to 189.60, giving 8.81% relief. This result was statistically significant as p<0.001. Triglycerides: The mean score of Triglycerides prior to treatment was 133.05, which was reduced to 124.90, giving 6.125% relief. This result was statistically significant at p<0.001. HDL: The mean score of HDL prior to treatment was 44.90, which was increase to 51.10, giving 12.13% relief. This result was statistically significant at p<0.001. LDL: The mean score of LDL prior to treatment was 116.25, which was reduced to 109.25, giving 6.021% relief. This result was statistically significant at p<0.001.

Effect of therapy on group B (Sarpagandha Churna)

Effect on blood pressure: Systolic Blood Pressure: The mean score of SBP was 158.80 and it reduced to 128.80 after treatment. The relief was 18.39% with giving significant result at p<0.001. Diastolic Blood Pressure: The mean score of DBP was 90.70 and it reduced to 79.60 after treatment. The relief was 12.24% with giving significant result at p<0.001. Pulse

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Pressure: The mean score of PP was 68.10 and it reduced to 48.10 after treatment. The relief was 29.36 % with giving significant result at p<0.001. Mean Arterial Pressure: The mean score of M.A.P was 113.40 and it reduced to 96.15 after treatment. The relief was 15.40% with giving significant result at p<0.001.

Effect on sign and symptom: Shiroruk (Headache): The mean score of Shiroruka was 1.45 and it reduced to 0.55 after treatment. The relief was 62.06% with giving significant result at p<0.001. Bhrama (Giddiness): The mean score of Bhrama was 1.45 and it reduced to 0.30 after treatment. The relief was 79.31% with giving significant result at p<0.05. Klama (fatigue): The mean score of Klama was 1.60 and it reduced to 0.80 after treatment. The relief was 50% with giving significant result at p<0.05. (Insomnia): The mean score of Anidra was 1.60 and it reduced to 0.80 after treatment. The relief was 75% with giving significant result p<0.05. Krodhaswabhava: The mean score Krodhaswabhaya was 1.00 and it reduced to 0.35 after treatment. The relief was 65% with giving significant result at p=0.001.

Effect on cholesterol: Total Cholesterol: The mean score of T. Cholesterol was 174.35, and it reduced to 170.50 after treatment. The relief was 5.22% with giving not significant result as p=0.751. Triglycerides: The mean score of Triglycerides was 141.40 and it reduced to 134.40 after treatment. The relief was 4.95% with giving significant result at p<0.001. HDL: The mean score of HDL was 44.90 and it increase to 51.10 after treatment. The relief was 13.80 % with giving significant result at p<0.001. LDL: The mean score of LDL was 118.55 and it reduced to 111.85 after treatment. The relief was 5.65 % with giving significant result at p<0.001.

Overall effect of therapy: Group A (trial Group) out of the 20 individuals in sign and symptom, 6 showed controlled relief, 12 showed marked reliefs and 2 moderate reliefs. In lowering Systolic blood pressure, 10 showed marked relief, 6 show moderate relief and 4 showed mild relief. In reducing Diastolic blood

pressure, 2 show moderately relief, 14 mild relief and 4 no relief. Percentage of relief of in T. Cholesterol, TGL, HDL and LDL are 9.48%, 6.125%, 8.36%, 6.021% respectively. Group - B: Out of 20 patients 7 showed control relief, 13 marked reliefs in sign and symptom; In lowering SBP, 3 showed controlled relief, 7 showed marked relief, 6 showed moderately relief and 4 showed mild relief: In reducing DBP 2 showed controlled relief, 14 showed marked relief, 2 showed moderately relief and 2 showed mild relief: Percentage of relief of in T. Cholesterol, TGL, HDL, and LDL are 5.22%, 4.95%, 6.90%, 5.65% respectively

Adverse effects: No adverse effects were observed in any patient throughout the study.

DISCUSSION

Essential Hypertension is a psychosomatic hemodynamic disease with a multi-factorial pathology and origin of several dietary, environmental and genetic factors. Numerous researches have been done, yet, there is a necessity for pursuing further research to find out some safe and effective therapy with no adverse effects and to prevent from life threatening complications of the Hypertension and save the Hypertensive population.

EHT is a Vata-Pitta Pradhana Tridoshaja Vyadhi and the main pathogenesis occurs in Rasa, Rakta Dhatu and Upadhatu (Sira and Dhamani). Vyana Vayu which is the main Vayu responsible for the maintenance or pumping function of the blood. It vitiation will lead over contraction of heart and increases of pressure in the blood vessel. If left untreated or its normal Gati it's not bring back to normal it will further causes Sankoch of Vahinies and by its Ruksha Guna it will dries up the inner Uplepa of Malarupa Kapha; enhances the process of Kathinya. Due to this there is narrow of pathway of circulation and Avarodha occurs in Rasa-Rakta Vikshepana Karma, causing forceful function of Vyana Vayu with increase of its Chala Guna. Due to which Vyana Vayu has to exert more pressure on the wall of Dhamani (blood vessels) to provide nourishment to different body part and lead to Essential Hypertension.

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After 21 days of treatment of Ashwagandhadi Churna 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 produced highly significant result in Shiroruka, Klama, Anidra, Bhrama and decrease in Irritability. Hence it can be concluded that Ashwagandhadi Churna brought significant changes in blood pressure with decrease of symptoms associated with essential hypertension and reduce in blood pressure to normal limits.

Probable mode of action of the drug

Probable mode of action of drugs may be because they have different pharmacodynamic properties due to which, multiple mechanism of actions taken place at different sites which may be responsible for of disruption pathogenesis of disease. Ashwagandhadi Churna with Ashwagandha as its main ingredients mainly acts on vitiated Vata Kapha Dosha but also has Pittahara properties because of Madhura Vipaka, Tikta Guna Phadhana and Sharkara contain in it, thereby helps to alleviate the Samprapti of disease. The drug act as Deepana, Pachana (Ashwagandha, Trikatu) properties helps to alleviate obstruction in the Strotasa due to Ama resulting into Stroto Shodhana and Vatanulomana. Ashwagandha is also having Mutrala properties thereby removing Kleda in the body and also reduces cardiac volume. The Whithanoloides extracts of Ashwagandha show significant effect in reducing serum cholesterol levels by its antioxidants properties, it does scavenging the free radicals, so that excess LDL are not oxidized inside the artery to form plague, thereby preventing atherosclerosis and other risk of coronary artery diseases, heart failure etc. On the other hand, significantly increased plasma **HDL-cholesterol** levels. [16] Ashwagandha is considered a nervine tonic with adaptogenic action, anti-stress properties, balances the stress hormones and reduces the cortisol levels and mitigates the stress induced hypertension. According to Mehra et al. (2009) reported that Ashwagandha is advocated as a protrective drugs against atherosclerosis, hypertension and coronry heart diseases. Ashwagandha alone is used for the treatment of mild and moderate Hypertension. The roots and leaves of Ashwagandha are used traditionally in the form of powder; decoction, oil etc are used in folk medicine against general disability, hypertension, inflammations and wounds.^[17]

Trikatu (Shunthi, Pippali, Marichi) has got a tremendous potential to increase the bioavailability of drugs and nutrients. It will help in action of main drugs by increasing the bioavailability of the drug across the membrane. Zingiber officinale has properties which improved blood circulation and relaxes muscles surrounding blood vessels lead to fall in the arterial BP. It has Ca²⁺ channel-blocking activity indicate that the BP lowering effect of ginger similar to the effect of verapamil.^[18]

CONCLUSION

Hypertension is Vata Pradhan Tridosha Vyadhi, Rasa Rakta as main Dushyas, Rasavaha, Raktavaha and Manovaha Srotasa as the main symptom involved. In Raktagata Vata the vitiated Vata get lodged in the Rakta Dhatu leading to Soshana of Rakta Dhatu. Ashwagandha have actions of scavenging free radicals, inhibit lipid peroxidation, delayed the plasma re-calcification time and enhances the release of lipoprotein lipase enzyme. It reduces the total cholesterol and triglycerides and increases high density lipoprotein cholesterol. In the present trial, Ashwagandhadi Churna show effective in the management of mild and moderate blood pressure and also effective in reducing blood Cholesterol Level. Ashwagandha alone is used for the treatment of mild and moderate Hypertension.

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