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Original Article

CLINICAL EFFICACY OF DRUG VYAN UTKSHEPAHARA GHAN VATI (KALPIT YOG) IN HYPERTENSION

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ABSTRACT

Due to the unwholesome diet, sedentary life style, day by day our country is facing the increasing burden of the patients of high blood pressure, diabetes and obesity. Our country is becoming the capital of these diseases. These diseases mostly treated by allopathic medicines which are having considerable side effects and could not be used on long term basis. So conclusion is that in these disease, the dose of allopathic medicines and disease gradually progresses and in addition due to the side effects of allopathic medicines, it is better that these diseases should be treated by Ayurvedic medicines. In this clinical trial 90 patients of hypertension were randomly selected and divided in to three groups. In Group A Vyan Utkshepahara Ghan Vati , In Group B Atenolol 50 mg and In Group C placebo drug had given to the patients. In all these three groups, group A was found as the most benefited because it showed significant as well as highly significant changes in symptoms and Biochemistry investigations. Whereas Group B (control group) showed significant as well as highly significant changes in symptoms but not in Biochemistry investigations. Placebo showed insignificant changes in both.

Key words:*Dhamani Prapurnata, Dhamani Pratichaya Raktagata Vata, Raktavritta Vata, Rasabhara Siragata Vata, Vyan Bala, Vyanavrita Vata. Vyan Vikriti.*

INTRODUCTION

High blood pressure (hypertension) is designated as either essential (primary) hypertension or secondary hypertension and is defined as a consistently elevated blood pressure exceeding 140/90 mm Hg. In essential hypertension (95% of people with hypertension) no specific cause is found. While secondary hypertension (5% of people with hypertension) is caused by an abnormality somewhere in the body such as in the kidney, adrenal gland aortic artery. High blood pressure is called "the Silent Killer"[1] because it often causes no symptoms for many years, even decades, until it finally damages certain critical organs like kidney, brain, blood vessel, eye etc. Mostly its diagnosis is ruled out all of sudden when the person comes in contact of doctor or health worker etc. Heightened public awareness and screening of the population are necessary to detect hypertension early enough so it can be treated before critical organs are damaged. It is one of the major risk factors for cardiovascular mortality, which accounts for 20-25% of all deaths.

AIMS AND OBJECTIVES

1. To evaluate the efficacy of *Ayurvedic* drugs as compare to modern drug, like Atenolol 50 mg.

2. To overcome the harmful effects of Allopathic drug in those patient which are suffering hypertension from long duration?

Selection of Patients

A total Ninety patient of Hypertension for clinical trial was screened out from OPD & IPD.

Grouping of Patient

Screened patient or the case registered for the study were randomly divided into three groups

Group A: This group of 30 patients had given the trial of drug *Vyan Utkshepahara Ghan Vati*.

Group B: This group of 30 patients had given the trial drug Atenolol 50 mg.

Group C: This group of 30 patients had given Placebo (VUHGV2)

During the trial and follow up study the patients were assessed on the following parameter.

Inclusion criteria

Patients with persistent rise of blood pressure with clinical picture of Hypertension have been selected for the research work.

Exclusion criteria

Patients' with severe grade of Hypertension. Mild or Moderate Hypertension associated with other diseases like Cardiomyopathy, Cardiac failure, Coronary artery disease, Heartblock, Cerebrovasculardisease,Encephalopathy,Preclampsia/eclampsia,Renaldisease,Diabetes mellitus and Diabetic Retinopathy.

Diagnostic criteria

To obtain diagnosis: On each occasion at least 2 sets of blood pressure reading, separated by 20-30 minutes intervals was taken. On the basis of 6th and 7th joint national committee on detection evaluation & treatment of high blood pressure.

JNC 6 Category		JNC 7 Category
	SBP / DBP in mm Hg	
Optimal	< 120 / 80	→ Normal
Normal	120 – 129 / 80 – 84	→ Pre hypertension
Border line	130 – 139 / 85-89	
Hypertension	≥ 140 / 90	Hypertension
Stage 1 (mild)	140 – 159 / 90 – 99	→ Stage I

Stage2 (moderate)	160 – 179 / 100 – 109	
Stage 3	≥ 180 / 110	→ Stage II

Subjective (clinical) Parameters:

Sirahashoola(Headache)*Bhrama*(Dizziness),*Hraddravata*(Palpitation),*Krodha*(Irritability),

Klama(Fatigue),*Anidra*(Insomnia),*Swasakrichhrata*(Dyspnoea),*Nishamutrata*(Nocturia),*Bahumutrata*(Polyuria),*Karnanada*(Tinitus),*Atisweda*(Sweating) and *Murchha* (Syncope) symptoms have been screened for diagnosis of Hypertension.

Assessment of Symptoms

Symptoms of the disease were assessed before and after the treatment on the basis of following criteria.

Not Present/Absence of Symptom	0	0
Very mild	1	25%
Mild	2	50%
Moderate	3	75%
Severe	4	100%

Assessment of Blood Pressure Reduction

The results of the treatment were assessed as striking, wonderful, nice and fair at the end of treatment. The parameters of the assessment were taken as follows: -

Striking: An excellent response to therapy when the fall in D.B.P. was found >20 mm Hg or more and S.B.P. >40 mm Hg.

Wonderful: When the patient was noticed with a good response to therapy when fall in D.B.P. was found 11-20 mm Hg and S.B.P. was 21-40 mm. Hg.

Nice: The response is named Nice when the fall in D.B.P. was 6 -10 mm Hg and S.B.P. was 11-20 mm. Hg.

Fair: When the response falls in D.B.P. up to 5 mm Hg and S.B.P. was up to 10 mm Hg.

Objective (Laboratory) Parameters

Complete Haemogram: Hb gm % TLC, DLC, ESR

Urine: Routine & Microscopic

Biochemical examination: S.urea, S.creatinine, Blood sugar fasting Lipid profile (S. cholesterol, S. triglyceride, S. HDL, S. LDL,S. VLDL

ECG - The entire test mentioned here has been done before and after treatment.

Ingredients of *Vyan Utkshepahara Ghan Vati*

Drug	Latin name	Proportion
Shankhapushpi	(*Convolvulus pluricaulis* Choisy)[2]	Equal part
Punarnava	(*Boerhavia diffusa* Linn.)[3]	Equal part
Vacha	(*Acorus calamus* Linn.)[4]	Equal part
Shunthi	(*Zingiber officinale* Roxb.)[5]	Equal part
Kutaki	(*Picrorhiza kurroa* Royle ex Benth.)[6]	Equal part
Patol	(*Trichoasathes dioica* Roxb.)[7]	Equal part
Guggulu	(*Commiphora mukul* Engl.)[8]	Equal part
Arjun	(*Terminalia arjuna* W. & A.)[9]	Equal part
Karela	(*Momordia charantia* Linn.)[10]	Equal part
Jamun	(*Syzygium cumini* Linn.)[11]	Equal part
Gudhchi	(*Tinospora cordifolia* (Willd) Miers.)[12]	Equal part

Preparation of Trial Drug

Vyan Utkshepahara Ghan Vati*:* After collection of Ingredients of *Vyan Utkshepahara Ghan Vati* (*Kalpit Yog*), it was manufactured & standardized according to vati preparation classical method in Indore pharmacy.

Method of preparation: The coarse powder of the above mentioned quantity of drugs had been taken separately according to the number of patients & then *Kasaya* followed by *Ghana Satva* is prepared by classical method & then pills (each pill 500 mg) are prepared & dried.

Dose	-	1 gm BD
Duration	-	2 months
Anupana	-	Luke warm water

Follow up: All the 90 patients of O.P.D. and I.P.D. level reviewed after two-month treatment. And on every review, blood pressure was measured in sitting posture for follow up records. Patients have been followed up after two month of study.

Observation and Results

The samples of 90 patients were selected and sub divided into 3 groups of 30 patients each. The treatment was observed according to the plan of the study. All the results were derived after execution of statistical techniques. The effect of each therapy is presented as follows: -

Effect of *Vyan Utkshepahara Ghan Vati,* Tab. Atenolol 50 mg and Placebo on S.B.P.

Table No. 1-In group A 30 patients were investigated for S.B.P. and an initial mean score of 159.67 mm of Hg was measured, after 2 month's treatment of *Vyan Utkshepahara Ghan Vati*, it reduced 145.53 mm of Hg with a mean difference of 14.14 mm of Hg with 8.85% of relief, it is highly significant ($t = 5.91$, $P<0.001$).

Group 'B'30 patients were investigated for initial mean score of S.B.P. was measured 157.73 mm of Hg and it reduced to 139.73 mm of Hg with 2 month treatment of atenolol 50 mg and mean difference of 18.00 mm of Hg and 11.41% of relief was observed. It is highly significant ($t = 12.19$, $P<0.001$).

Initial mean score of Group C (for30 patients) S.B.P. was measured 156.6 mm of Hg and after 2 month treatment of placebo is reduced to 153.03 mm of Hg and a mean different of 3.56 mm of Hg was found and 2.27% of relief was found. It is insignificant ($t =1.61$, $P<0.1$)

Effect of *Vyan Utkshepahara Ghan Vati,* Tab. Atenolol 50 mg and Placebo on D.B.P.

Table No. 2-In group A 30 patients were investigated for D.B.P. and an initial mean score of 94.73 mm of Hg D.B.P. was measured, after 2 month treatment of *Vyan Utkshepahara Ghan Vati* it reduced to 89.26 mm of Hg with a mean difference of 5.47 mm of Hg and 5.78% of relief. It is highly significant ($t = 4.32$, $P<0.001$).

In group B's initial mean score D.B.P. was measured 95.40 mm of Hg and it reduced to 88.20 mm of Hg with 2 month treatment of atenolol 50mg and mean difference of 7.20 mm of Hg and 7.55 % of relief was observed. It is highly Significant ($t = 8.16$, $P<0.001$)

Initial mean score of group C's D.B.P. was measured 88.66 mm of Hg and after 2 month treatment of placebo is reduced to 86.53 mm of Hg and a mean difference of 2.13 mm of Hg was found and 2.40% of relief was found. It is insignificant ($t =0 .1$, $P<0.001$)

Bio-Chemistry Tests -Table No. 5-7.

Biological values: After two month of trial there are no significant changes in Hb and TLC. *Vyan Utkshepahara Ghan Vati* and Control drug Therapy showed statistically significant decrease in ESR. (Table-9-10**)**

DISCUSSION

Ayurvedic treatment is a better remedy than Allopathic because generally Allopathic medicines are given after diagnosis of symptoms, whereas *Ayurvedic* remedies are given after analyzing the cause or root of the problem. To understand the various causes of hypertension from the *Ayurvedic* point of view it is necessary to understand its basic fundamental principles. Hypertension may also be classified according the main *Dosha* involved and its site of origin. The main site of *Vata* is the large intestine. When *Vata* and accumulates it can be absorbed into the blood increasing the qualities of *Vata* and causing constriction of the blood vessel walls. Constriction of the blood vessels may also be a result of *Vata* increasing due to psychological stress associated with fear, anxiety and insecurity. The small intestine is the main site of *Pitta*. If

Pitta accumulates here it is absorbed into the circulatory system increasing the viscous, fatty oily qualities. Due to the increased viscosity, the blood exerts pressure on the blood vessels resulting in increased blood pressure. *Pitta* can also increase due to psychological stress related to anger, hate, envy and jealousy may be associated with increase blood pressure.*Kapha* type hypertension originates in the stomach being the main site of *Kapha. Kledaka Kapha* produced in the stomach in the form of gastric mucosal secretions that are responsible for the digestion of carbohydrates, starch and glucose. The end products of this phase are tryglycerides. When *Kledaka Kapha* is disturbed or there is an accumulation of *Kapha* at this site, there is an accumulation of triglycerides and cholesterol. This accumulation of *Kapha* predominant qualities then move into the circulatory system causing an increase in the viscosity of plasma tissue within the blood resulting in increased pressure on the blood vessels.*Ayurveda* recognizes that the mind has a strong influence on the heart. If an individual is under psychological stress, this can lead to the onset of hypertension. Mental tension accumulates in the physical body via the brain which is the gateway between the mind and body. This function is governed by *Prana Vayu* and controls the autonomic nervous system which is responsible for blood pressure regulation. The brain normally programs the body by sending excitatory and inhibitory impulses to certain areas, and by regulating the balance of the autonomic and sensory motor components of the nervous system. When *Prana Vayu* is disturbed, hypertension can occur due to excessive sympathetic stimulation. Disturbed *Prana Vayu* also relates to all psychosomatic diseases which are caused by the unbalancing and disorganization of mental processes that proceed as though they were disconnected from our control. Hypertension may also be a result of heredity and lifestyle due to developed mental patterns of unwholesome living habits which affect the circuits of the brain leading to hypertension. The perception or mind can affect our body's response and lead to a balanced or imbalanced state of health. Environmental stimulus creates impression on the mind which leads to psychological response effects on the body altering the following centres:

1-Limbic system 2-Hypothalamus 3-Neuroendocrine system 4-Long term Effect on Body 5-Altered Immune Function

An important factor to be considered when establishing the cause and reason for the manifestation of disease in a particular part of the body is the concept of *Khavaigunya*. *Khavaigunya* corresponds to a *Dhatu* or area of the body being more susceptible to disease or imbalance. This helps to understand why a particular tissue is affected and its origin.For example there may be a genetic predisposition in the family (*Beej Doshaja*),long standing or acute exposure to environmental, physical or psychological stressors causing the tissue to be inherently weak or weakened, which explains why that particular site has become vitiated. Therefore any disease can be caused by one particular *Dosha* or a combination of the three. When the *Dosha's* become aggravated through food, lifestyle or attitude, the nature of that substance leads to an increase of similar qualities inherent in the body and mind. The accumulation of these qualities according to *Ayurveda* is first stage of disease.

In more than 95% of cases of specific underlying causes of hypertension cannot be found (essential hypertension) the pathogenesis of essential hypertension is not clearly understood. Non modifiable risk factor like age, sex, genetic factor, ethnicity & modifiable risk factor like obesity salt intake, Saturated fat, alcohol, heart rate, physical activity, environmental stress, socioeconomic status, dietary fibers & other factor explain approximately 40 - 60 %. 5% of hypertensive patient have identifiable causes like endocrinal (Diabetes) renal, cardiovascular disease, & drugs induce etc.

Hence the constituents of these drugs are selected in a holistic approach for all kinds of hypertensive patients.

Shankhapushpi (C*onvolvulus pluricaulis* Choisy.)-help to treat stress induced hypertension (C.N.S origin)[13]

Punarnava (*Boerhavia diffusa* Linn.) - help to treat renal induced hypertension.[14]

Vacha (*Acorus calamus* Linn.) help to treat stress induced hypertension (C.N.S origin)[15]

Shunthi (*Zingiber officinale* Roxb.) - help to treat Toxins induced hypertension.[16]

Kutaki (*Picrohiza kurroa* Royle ex Benth.) help to treat Blood volume induced hypertension.[17]

Patol (*Trichoasathes dioica* Roxb.) help to treat Diabetic induced hypertension.[18]

Guggulu (*Commiphora mukul* Engl.) - help to treat Obesity induced hypertension.[19]

Arjun (*Terminalia arjuna* W. & A.) - help to treat cardiac induced hypertension.[20]

Karela (*Momordia charantia* Linn.) - help to treat Diabetic induced hypertension.[21]

Jamun (*Syzygium cumini* Linn.) - help to treat Diabetic induced hypertension.[22]

Gudhchi (*Tinospora cordifolia* (Willd) Miers.) - help to treat auto immune induced hypertension.[23]

Dipana – Pacana Drugs it is clear that *Agnimandya* is a prime factor for production of Hypertension. *Dipana Pacana Drugs (Shunthi etc)* improve the status of *Agni*.

Lekhana Drugs having *Srotosodhaka* & weight reducing properties which help to treatment of hypertension. *(*Drugs like *Guggulu Kutaki etc)*

Virechana: Kostha Suddhi is very importance in treating a patient of Hypertension. The elimination of *Doshas* and *Mala* from body by *Virechana Karma, Virechana Karma* reduce the increase blood volume induced Hypertension. (*Example Kutaki*)

Tridosha Samana: Hypertension is *Tridoshaja Vyadhi* but most vitiated and dominant *Doshas* are V*ata & Kapha*, those drugs which have *Tridoshsamaka* properties use to treat hypertensive patient *(Drug like Shunthi)*

Rasayana Therapy:*Rasayna* help to protect *Oja*, improve *Agni,*cleans the microcirulatory channels etc. all these developments help in producing tranquility of mind and thus reducing Hypertension, *Rasayans (Chyawanprash etc.)* increase the *Medha (Buddhi)* is called *Medhya (Drugs like Shankhpuspi Jatamansi etc.)* help to treat stress induced hypertension.

Srotosodhana: *Rasayan* like *Guduchi* etc. *Mutrala* Drugs (Diuretics like *Punarnava*) Reduce the vascular volume by diuresis which ultimately influence the blood pressure.

Hridya Drugs (Cardiotonic) these drugs increase *Oja & Avalambaka Kapha*. & are beneficial for heart is known as *Hridya* like *Arjun* etc. Uses of Antidiabetic drug like *Karela* in case of Diabetic induced Hypertension .Uses of G*uggulu* preparation for obesity induced hypertension.

The result of the final study reveals better efficacy of *Vyan Utkshepahara Ghan Vati*. Fruther correlation in terms of S. Creatinine, S.Urea,and S.cholesterol etc. also confirms the efficacy of *Vyan Utkshepahara Ghan Vati*. The efficacy of *Vyan Utkshepahara Ghan Vati* in hypertension has been due to its ingredients; S*hankhpuspi, Punarnava, Vacha, Shunthi, Kutaki, Patol, Guggulu, Arjuna, Karela, Jamun and gudhchi* directly or indirectly affects on blood pressure. The desired Pharmacological effect also shows the genuine nature of medicament. The present study being of explanatory nature no firm reacting result can be desired. Further study in this respect shall have the way to pin point role of all the drugs in Hypertension. Now discussion, on the basis of following observations found in this study.

Age: In our study majority of patients were of 41-50 years of age in male and 41 - 50 years of age in female were found. It indicates that Hypertension increases with age, as described in *Astang Samgraha* that in old age *Vata* is the predominating *Dosha* .

Sex: Out of 90 patients 47 (52.22%) were male and 43 (47.77%) were female. For this difference in gender we can say that:

Monthly menses keeps fluid volume slightly lower in women, so that homodynamic cascade towards hypertension is slowed. And on the basis of this gender based difference we can compare the situation under which Hypertension is more likely to create.

Religion: In a religion wise study it was found that 83.33% (75) patients were *Hindu* and 16.66 %(15) patients were *Muslim* since the patients were collected from the *Hindu* dominating area.

Socio-economic status: By studying the socio-economic status of 90 patients it was found that middle classes are more prone (34.44%) to hypertension. And the upper middle class had (34.44%) these two classes generally remain undergoes sedentary life style. which produces *Ama* lead to hypertension.

Occupation: In the study based on occupational distribution it has been noticed that housewives (18.88%) are more prone to hypertension than any other working classes. Most possibly it was due to heightened stress, strain and less medical awareness.

Educational Status: After making the observation of 90 patients it was found that 9 patients were illiterate and 81 were literate. Illiterates had limited source of income and literates spent more than their economic capability. Thus both sustained stress.

Marital Status: Out of 90 cases 81 married patients with H.T. were found and only 9 were there who were unmarried it may be because the married people have more responsibilities and worldly worries that creates tension.

***Akriti*:** In this study we found that a maximum number of 41 patients (45.55%) were from *Sthula Sharira Aakriti* .Probably due to obesity is a Risk factors for hypertension.

Severity of Hypertension: A comparisons on the base of mild and moderate conditions of the patients it was noticed that72 patients (80%) of cases were found moderate and only 20% were of mild Hypertension. It can be said that older the case severe the case.

Treatment History: The present study based on the patient's drug taking shows us that out of 90 patients, 58 were in habit of taking antihypertensive drugs whereas 32 were noticed without taking any drug means these 32 were the fresh cases or the patients who were not familiar with the problem of Hypertension with which they were suffering.

Dietary Habit: In this study mixed dietary habits were comparatively more prone the developed hypertension than the persons with vegetarian but it is not so clear why mixed dietary habits were more prone to hypertension. Probably it may be due to its increases *Meda* and *Mamsa Dhatu* in the body, which increases blood pressure.

***Anidra*:** Out of 90 patients 41 (45.55%) were found suffering from *Anidra* problem. It appears they suffered from family problems or economic problems thus causing more stress and consequently they suffered *Anidra*.

***Kostha*:** Maximum i.e. 46.66% patients were having *Krura Kostha*.

Agni: When the Agni based observations were made it was found that out of 90 patients 25 were having *Sama Agni*, whereas 32 (35.55%) were having the *Vishamagn*i that is also an effective factor of Hypertension. due to *Vishamagni Ama* formation occurs.

More intake of salt in diet: Study shows that *Lavana rasa* users were 30 (33.33%) and *Madhura Rasa* users were 23(25.55%) out of total 90 patients. It has been informed that *Lavana Rasa* increased the total body fluid as we have already noted.

Family History: Positive family history was present in 46.66% patients that showed genetic predisposition is an important etiological factor in development of Hypertension.

Addiction: The collected data showed that maximum numbers of patients were Tea, smoking, Tobacco and alcohol addict.

Stress: The collected data demonstrated that maximum patients (60%) in group A 50% in Group B and in Group C is 56.66% were having stress, which may affect homeostasis of body and mind towards some psychological disorder like Hypertension.

***Habitat*:** The study revealed that maximum patients (86.66%) were living in urban area; due to their mechanical and speedy life has major impact on all aspects of their life leading to psychosomatic disorders like Hypertension.

***Sharirika Prakriti*:** In this study we found that a maximum number of (37.77%) were from *Vata Pitta Prakriti*.

Vata Prakriti is more prone to develop disease due to its *Vata Ansha* and more prone to develop psychic stress and emotional disturbances due to both *Vata and Pitta Ansha*.

Manasa Prakriti: Maximum patients (56.66%) were *Rajasika Prakriti* and 40% of *Tamsika prakriti.* In *Rajasika Prakriti* due to excess of "*Rosha Ansha"* all emotions like *Krodha, Shoka, Bhaya, Chinta* etc. appear in them in their full-exaggerated form and they can face the critical stressful situation after consolation or after being convinced by someone. So they are more prone to develop psychosomatic disorders. *Tamsika Prakriti*, due to excess of "*Moha Ansha*" cannot tolerate even a little stress and also it is very hard to convince or console them. Therefore, a little trouble can disturb their lives and they may suffer from a psychosomatic disorder easily.

***Sara-Samhanan-Satmya-Satva*:** The study shows that maximum number of patients was *Madhyama Sara, Madhyam Samhanana, Madhyama Satmya* and *Madhyam Satva* so that type of person easily got the disease compare to pravara sara-samhnanana-satmya Satva.

Symptoms: In our study *Shirahsoola, Anidra,Bhrama, krodha, Swaskrichhrata , Hriddravat* were very common among the patients these complain were 81.11%, 80%, 55.55%, 47.77%, 44.44% and 43.33% respectively where as other complaints were also frequent like *Bahumutrata,Klama, Atisweda,Nishamutrata and Karnanada* 25.55%, 24.44%, 22.22%, 16.66% & 13.33% respectively.

Effect of Therapies: The effect of Therapies on three groups on various parameters, were as follows:

Systolic Blood Pressure: *Vyan Utkshepahara Ghan Vati* provided 8.85 mean percentage reduction in systolic blood pressure in Group A, tablet Atenolol 50mg provided 11.41mean percentage reduction in systolic blood pressure in group B. and in Placebo Group C provided 2.27 mean percentage reduction. GroupA and Group B therapies were statistically highly significant (P<0.001).

Diastolic Blood Pressure: *Vyan Utkshepahara Ghan Vati* provided 5.78 mean percentage reduction Diastolic blood pressure in Group A, tablet Atenolol 50mg provided 7.55 mean percentage reduction in diastolic blood pressure in group B. Placebo Group C provided 2.40 mean percentage reduction. Group A and Group B therapies were statistically highly significant (P<0.001).

Symptoms

***Shirahshoola*:** *Vyan Utkshepahara Ghan Vati* provided 72.2 mean percentage reduction *Shirahshoola* in Group A, tablet Atenolol 50mg provided 82.2 mean percentage reduction in *Shirahshoola* in group B. and in Placebo Group C provided 20.63 mean percentage reduction in *Shirahshoola*. Group A and Group B therapies were statistically highly significant (P<0.001). (table -3&4).

***Bhrama*:** *Vyan Utkshepahara Ghan Vati* provided 67 mean percentage reduction *Bhrama* in Group A, tablet Atenolol 50mg provided 83.13 mean percentage reduction in *Bhrama* in group B. and in Placebo Group C provided 16 mean percentage reduction in. *Bhrama* Group A and Group B therapies were statistically highly significant (P<0.001) (table -3&4).

***Karnanada*:** *Vyan Utkshepahara Ghan Vati* provided 52.17 mean percentage reduction *Karnanada* in Group A, tablet Atenolol 50mg provided 77.77 mean percentage reduction in *Karnanada* in group B. and in Placebo Group C provided 9 mean percentage reduction in *Karnanada*. Group A and Group B therapies were statistically highly significant (P<0.001) (table-3&4).

***Krodha*:** *Vyan Utkshepahara Ghan Vati* provided 58.4 mean percentage reduction *Krodha* in Group A, tablet Atenolol 50mg provided 61.9 mean percentage reduction in *Krodha* in groupB. and in Placebo Group C provided 22.58 mean percentage reduction in *Krodha*. Group A and Group B therapies were statistically highly significant (P<0.001) (table -3&4).

Klama: *Vyan Utkshepahara Ghan Vati* provided 53.12 mean percentage reduction *Klama* in Group A, tablet Atenolol 50mg provided 59 mean percentage reduction in *Klama* in group B. and in Placebo Group C

provided 15.87 mean percentage reduction in *Klama*. Group A and Group B therapies were statistically highly significant (P<0.001) (table -3&4).

Hriddrava: *Vyan Utkshepahara Ghan Vati* provided 58.33 mean percentage reduction *Hriddrava* in Group A, tablet Atenolol 50mg provided 70 mean percentage reduction in *Hriddrava* in group B. and in Placebo Group C provided 14.28 mean percentage reduction in *Hriddrava*. Group A and Group B therapies were statistically highly significant (P<0.001 (table -3&4)

Anidra**:** *Vyan Utkshepahara Ghan Vati provided* 53.48 mean percentage reduction *Anidra* in Group A, tablet Atenolol 50mg provided 62.63 mean percentage reduction in *Anidra* in group B. and in Placebo Group C provided 11.62 mean percentage reduction in *Anidra*. Group A and Group B therapies were statistically highly significant (P<0.001 (table -3&4).

Swasakrichhrata: *Vyan Utkshepahara Ghan Vati* provided 26.15 mean percentage reduction Swasakrichhrata in Group A, tablet Atenolol 50mg provided 61.90 mean percentage reduction in *Swasakrichhrata* in group B. and in Placebo Group C provided 18.33 mean percentage reduction in *Swasakrichhrata*. Group A and Group B therapies were statistically significant and highly significant respectively. (P<0.02 P<0.001 (table -3&4)

Nishamutrata**:** *Vyan Utkshepahara Ghan Vati* provided 40.00 mean percentage reduction *Nishamutrata* a in Group A. tablet Atenolol 50mg provided 55.55 mean percentage reduction in *Nishamutrata* a in group B. and in Placebo Group C provided 19.04 mean percentage reduction in *Nishamutrata*. GroupA and Group B therapies were statistically significant and highly significant respectively. (P<0.02 P<0.001 (table -3&4).

Bahumutrata:*Vyan Utkshepahara Ghan Vati* provided 29.04 mean percentage reduction *Bahumutrata* in Group A. tablet Atenolol 50mg provided 58.49 mean percentage reduction in *Bahumutrata* a in group B. and in Placebo Group C provided 21.56 mean percentage reduction in *Bahumutrata*. Group A and Group B therapies were statistically significant and highly significant respectively. (P<0.02 P<0.001) (table -3&4).

Atisweda: *Vyan Utkshepahara Ghan Vati* provided 28.57 mean percentage reduction Atisweda an in Group A. tablet Atenolol 50mg provided 50.00 mean percentage reduction in *Atisweda* an in group B. and in Placebo Group C provided 19.23 mean percentage reduction in *Atisweda*. Group A and Group B therapies were statistically significant and highly significant respectively. (P<0.05 P<0.001) (table-3 &4).

(A) Serum Cholesterol. Group A had highly significant reduction of 9.78%, (t = 5.41, P<0.001); Group A had also highly significant reduction of 9.78%, (t= 5.41 P<0.001). Whereas Group B and Group C were found with insignificant decrease 2.69% (t=1.51, P< 0.10) and 3.68% (t=1.28, P=<0.20) respectively (table-5, 6&7).

(B) Serum Triglyceride: It was investigated that Group A are highly significant. Group A had a significant decrease of 4.87%, (t = 4.09, P<0.001). Group B had an insignificant decrease of 2.78%, (t = 1.54, P<0.10) and Group C had an insignificant decrease of 2.33 % (t=1.24, P<0.20) (table-5, 6&7).

(C) Serum High Density Lipid (HDL): After the investigation it was being found that group A had highly significant reduction of 25.59% (t = 3.67, P<0.001); whereas Group B and Group C were found with insignificant decrease 13.91% (t=1.64, P< 0.10) and 5.16% (t=1.21, P=<0.20) respectively (table-5, 6&7).

(D) Serum Low Density Lipid (S.L.D.L.): Investigations show that group A had significant reduction of 4.92%, (t = 2.35, P<0.02); Group B had also insignificant reduction of 2.61%, (t= 1.25, P<0.20). Group C were found with insignificant decrease 2.12% (t=1.01, P<0.30) (table-5, 6&7).

(E) Serum Very Low Density lipid (S.V.L. D. L.): After the investigations it was found that group A had significant reduction of 10.32%, (t = 2.13, P<0.02); whereas Group B and Group C were found with insignificant decrease 8.24% (t=1.57, P< 0.10) and 7.99% (t=1.46, P=<0.10) respectively (table-5, 6&7).

(F) Serum Creatinine: Investigations show that group A had insignificant reduction of 7.94%, (t = 1.44, P<0.10); whereas Group B and Group C were found with insignificant decrease 2.97% (t=1.09, P< 0.20) and 2.54% (t=1.00, P=<0.30) respectively (table-5, 6&7).

(G) Serum Urea: After the investigation it was found that group A had significant reduction of 10.41%, (t = 1.77, P<0.05); whereas Group B and Group C were found with insignificant decrease 9.14% (t=1.55, P< 0.10) and 6.23% (t=1.00, P=<0.30) respectively (table-5, 6&7).

(H) Fasting Blood Sugar: After making the investigations it was found that group A had highly significant reduction of 15.69%, (t = 4.43, P<0.001); whereas Group B and Group C were found with insignificant decrease 2.55% (t=1.29, P< 0.20) and 1.72% (t=0.88, P=<0.30) respectively (table-5, 6&7).

Table 1: Showing the statistically analysis of the effect of trial drug,control drug, and placebo on S.B.P.

Group	Mean		Mean Diff.	Mean %	n	SD	SE	t	p	Results
	BT	AT								
A	159.67	145.53	14.14	8.85	30	13.07	2.39	5.91	<0.001	HS
B	157.73	139.73	18.00	11.41	30	8.085	1.476	12.19	<0.001	HS
C	156.6	153.03	3.56	2.27	30	12.12	2.21	1.61	<0.1	IS

Note: HS: Highly Significant, S: Significant, IS: Insignificant

Table 2: Showing the statistically analysis of the effect of Vyan Utkshepahara Ghan Vati , Tab. Atenolol 50 mg and Placebo on D.B.P.

Group	Mean		Mean Diff.	Mean %	n	SD	SE	t	p	Results
	BT	AT								
A	94.73	89.26	5.47	5.78	30	6.93	1.27	4.32	<0.001	HS
B	95.40	88.20	7.20	7.55	30	4.830	0.882	8.16	<0.001	HS
C	88.66	86.53	2.13	2.40	30	6.96	1.27	1.67	<0.1	IS

Table 3: Showing mean percentage relief in Symptoms after two month clinical trial group,control group,and Placebo group.

S. No.	Group A	Group B	Group C
Sirahshoola	72.2%,	82.2%	20.63%
Bhrama	67.00%	83.13%	16.00%
Tinnitus	52.17%	77.77%	9.00%
Krodha	58.4%	61.9%	22.58%
Klama	53.12%	59.00%	15.87%
Hriddrava	58.33%	70.00%	14.28%
Anidra	53.48%	62.63%	11.62%
Swaskrichhrata	26.15%	61.90%	18.33%
Nishamutrata	40.00%	55.55%	19.04%
Bahumutrata	29.03%	58.49%	21.56%
Atisweda	28.57%	50.00%	19.23%

Table 4: Show t value and P value of the symptoms after two month clinical trial (if P value<0.20 to >0.05=insignificant, if P value≤0.05 to >0.01=significant, if P value ≤0.01 to <0.001= highly significant*)*

Symptoms	GROUP A		Results	GROUP B		Results	GROUP C		Results
	t value	P value		T value	P value		t value	P value	
Sirahshoola	10.43	<.001	H.S	12.49	<.001	H.S	1.47	<.10	I.S
Bhrama	9.74	<.001	H.S	12.81	<.001	H.S	1.58	<.10	I.S
Tinnitus	6.00	<.001	H.S	6.42	<.001	H.S	0.75	<.10	I.S
Krodha	9.34	<.001	H.S	12.80	<.001	H.S	1.66	<.10	I.S
Klama	5.57	<.001	H.S	7.94	<.001	H.S	1.55	<.10	I.S
Hriddrava	7.70	<.001	H.S	10.12	<.001	H.S	1.47	<.10	I.S
Anidra	8.02	<.001	H.S	12.85	<.001	H.S	1.44	<.10	I.S
Swaskrichhata	2.37	<.02	S	7.21	<.001	H.S	1.59	<.10	I.S
Nishamutrata	2.87	<.02	S	5.00	<.001	H.S	1.17	<.20	I.S
Bahumutrata	2.43	<.02	S	7.03	<.001	H.S	1.60	<.10	I.S
Atisweda	1.97	<.05	S	6.04	<.001	H.S	1.23	<.20	I.S

Table 5: Showing the effect of Trial Drug *(Vyan Utkshepahara Ghan Vati)* of Group A.

S.No.	Test	Mean		Mean Diff.	Mean %	n	SD	SE	t	Results
		BT	AT							
1.	S. Cho.	175.73	158.53	17.2	9.78	30	17.40	3.17	5.41	<0.001
2.	S. Tg.	150.33	143.00	7.33	4.87	30	9.80	1.78	4.09	<0.001
3.	S. HDL	43.50	54.63	11.13	25.59	30	16.58	3.02	3.67	<0.001
4.	S. LDL	88.00	83.66	4.33	4.92	30	10.06	1.83	2.35	<0.02
5.	S. VLDL	33.56	30.1	3.46	10.32	30	8.88	1.62	2.13	<0.02
6.	S.Creatinine	0.79	0.73	0.06	7.94	30	0.239	0.043	1.44	<0.10
7.	S. Urea	32	28.66	3.33	10.41	30	10.30	1.88	1.77	<0.05
8.	F.B.S.	86.20	72.66	13.53	15.69	30	16.73	3.05	4.43	<0.001

Table 6: Showing the effect of control drug (Atenolol 50mg) on Group B.

S.No.	Test	Mean		Mean Diff.	Mean %	n	SD	SE	t	Results
		BT	AT							
1.	S. Cho.	171	166.4	4.6	2.69	30	16.64	3.03	1.51	<0.10
2.	S. Tg.	148.66	144.53	4.13	2.78	30	14.64	2.67	1.54	<0.10
3.	S. HDL	50.3	57.3	7.00	13.91	30	23.24	4.24	1.64	<0.10
4.	S. LDL	95.63	93.13	2.49	2.61	30	10.90	1.99	1.25	<0.20
5.	S. VLDL	33.56	30.8	2.76	8.24	30	9.63	1.75	1.57	<0.10
6.	S.Creatinine	0.783	0.76	0.023	2.97	30	0.116	0.021	1.09	<0.20
7.	S. Urea	32.06	29.13	2.93	9.14	30	10.32	1.88	1.55	<0.10
8.	F.B.S.	80.73	78.66	2.07	2.55	30	8.70	1.59	1.29	<0.20

Table 7: Showing the effect of Placebo Therapy on Group C

S.No.	Test	Mean		Mean Diff.	Mean %	n	SD	SE	t	Results
		BT	AT							
1.	S. Cho.	177.2	170.66	6.53	3.68	30	27.77	5.07	1.28	<0.20
2.	S. Tg.	148.66	145.2	3.46	2.33	30	15.28	2.79	1.24	<0.20
3.	S. HDL	57.46	54.5	2.96	5.16	30	13.37	2.44	1.21	<0.20
4.	S. LDL	95.66	93.63	2.03	2.12	30	10.99	2.00	1.01	<0.30
5.	S. VLDL	35.03	32.23	2.8	7.99	30	10.46	1.91	1.46	<0.10
6.	S.Creatinine	0.786	0.766	0.020	2.54	30	0.112	0.020	1.00	<0.30
7.	S. Urea	32.06	30.06	2.00	6.23	30	10.93	1.99	1.00	<0.30
8.	F.B.S.	81.03	79.63	1.4	1.72	30	8.72	1.59	0.88	<0.30

Table 8: Showing the effect of Trial Drug *(Vyan Utkshepahara Ghan Vati)* on Hb, TLC & ESR in group A.

Group	Test	Mean		Mean Diff.	Mean %	n	SD	SE	t	p	Results
		BT	AT								
A	Hb gm%	11.77	11.98	0.21	1.84	30	0.806	0.147	1.47	<0.10	I.S
B	TLC	8046	7851	194	2.41	30	712	130	1.49	<0.10	I.S
C	ESR	16.06	14.53	1.53	9.54	30	4.33	0.791	1.93	<0.05	S

Table 9: Showing the effect Atenolol 50 mg on Hb, TLC & ESR in Group B.

Group	Test	Mean		Mean Diff.	Mean %	n	SD	SE	t	p	Results
		BT	AT								
A	Hb gm%	11.83	12.08	0.25	2.11	30	0.858	0.156	1.59	<0.10	I.S
B	TLC	8004	7808	196	2.44	30	665.67	121.53	1.61	<0.10	I.S
C	ESR	16.2	14.53	1.66	10.28	30	4.46	0.815	2.04	<0.05	S

Table 10: Showing effect of Placebo on Hb, TLC & ESR group C.

Group	Test	Mean		Mean Diff.	Mean %	n	SD	SE	t	p	Results
		BT	AT								
A	Hb gm%	11.86	12.10	0.233	1.96	30	1.00	0.183	1.27	<0.20	I.S

B	TLC	8021	7886	135	1.68	30	614.76	112.24	1.20	<0.20	I.S
C	ESR	16.2	15.06	1.13	6.99	30	4.86	0.887	1.27	<0.20	I.S

Table 11: Showing the Percentage of striking, wonderful, nice and fair in all three groups in S.B.P.

S. No	Response	No. of Patients with reduction in SBP					
		Group A n=30	%	Group B n=30	%	Group C n=30	%
1.	Striking	9	30.00	15	50.00	0	00.00
2.	Wonderful	15	50.00	10	33.33	1	03.33
3.	Nice	5	16.66	4	13.33	2	06.66
4.	Fair	1	03.33	1	03.33	17	56.66
5.	No response	0	00.00	0	00.00	10	33.33

Figure 1: Showing the Percentage of striking, wonderful, nice and fair in all three groups in S.B.P.

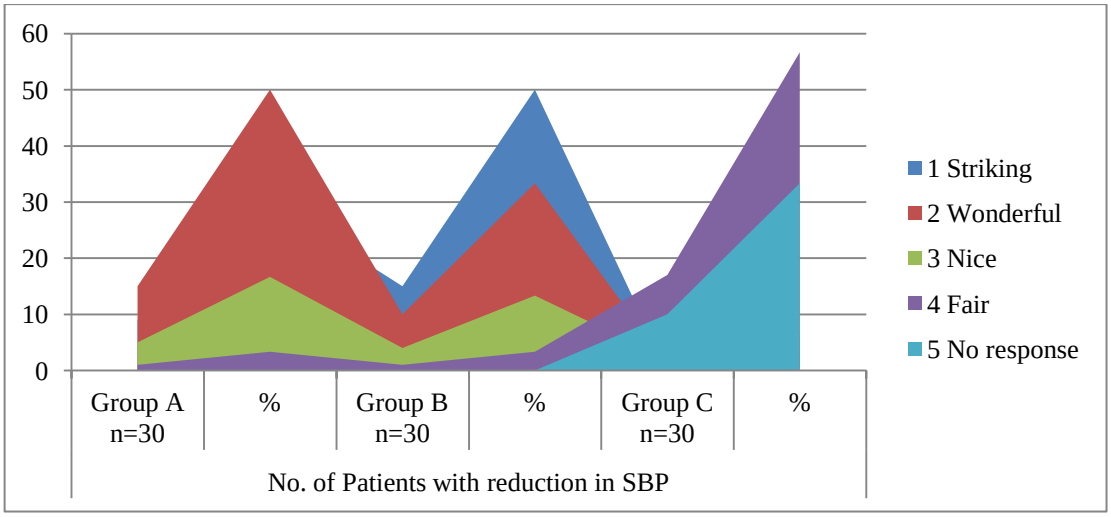
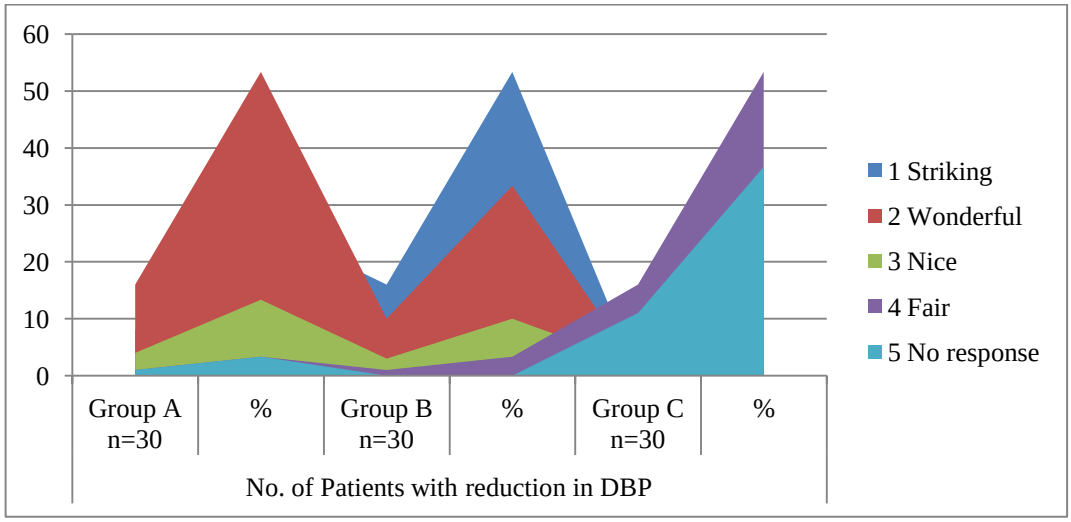


Table 12: Showing the Percentage of striking, wonderful, nice and fair in all three groups in D.B.P.

S. No	Response	No. of Patients with reduction in DBP					
		Group A n=30	%	Group B n=30	%	Group C n=30	%
1.	Striking	8	26.66	16	53.33	0	00.00
2.	Wonderful	16	53.33	10	33.33	1	03.33
3.	Nice	4	13.33	3	10.00	2	06.66
4.	Fair	1	03.33	1	03.33	16	53.33
5.	No response	1	03.33	0	00.00	11	36.66

Figure 2:Showing the Percentage of striking, wonderful, nice and fair in all three groups in D.B.P



CONCLUSION

In all the three groups, group A was found as the most benefited group because it showed significant as well as highly significant changes in symptoms and Biochemistry investigations. Whereas Group B (control group) showed significant as well as highly significant changes in symptoms but not in Biochemistry investigations. Placebo showed insignificant changes in both.

The drug *Vyan Utkshepahara Ghan Vati* is a safe herbal formulation and has shown encouraging results in the management of Hypertension on various scientific parameters.

While *Vyan Utkshepahara Ghan Vati"*reduced both systolic and diastolic pressure in a more pronounced way, Furthermore, it was also found during treatment that some of patients improved to such an extent that they had either stopped the modern antihypertensive drug completely or minimized its dose suggesting that the drug. Thus being helpful in avoiding the side effects of modern drug too.

The plus point observed in case of *Ayurvedic* management is absence of any hazardous effect, which is really a great benefit to the patient.

It offers the possibility of effectiveness & very well tolerated therapy ensuring reliability & good acceptance in use therefore on point of view of *Ayurvedic* treatment by *Vyan Utkshepahara Ghan Vati* may be accepted as the drug of choice in the case of mild and moderate hypertension.

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