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Original Research Paper

Ayurveda

A CLINICAL EVALUATION OF A TRADITIONAL HERB*CLERODENDRUM GLANDULOSUM LINDL.*(*CLERODENDRUM COLEBROOKIANUM* WALP) IN THE MANAGEMENT OF MILD TO MODERATE CASES OF ESSENTIAL HYPERTENSION

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ABSTRACT

Essential Hypertension is a chronic and often asymptomatic clinical condition in which systemic arterial blood pressure elevated beyond normal. The increased blood pressure in the arteries depends upon a persons age, sex, physical and mental activities, family history and diet etc. Primary or essential hypertension is the world's leading risk factor for global disease burden, is expected to cause more than half of the estimated 17 million deaths per year resulting from cardiovascular disease worldwide. Some traditional herbs used by north east people shows satisfactory result in treatment of various life threatening disease. *Clerodendrum glandulosum*Lindl. is one of those traditional herbs used as vegetables by more then 20 tribes of north east region and they claim that low incidence of hypertension due to regular intake of this herb.A clinical study was conducted among 86 cases of uncomplicated mild to moderate hypertension were randomly selected from OPD and IPD of Kayachikitsa Deptt, Govt. Ayurvedic College & Hospital Guwahati-14, Assam. The data shows significant improvement on management of essential hypertension and no complications were found during and after the clinical study.

KEYWORDS : Essential Hypertension,Clerodendrum glandulosum Lindl, Clinical Study

INTRODUCTION

In modern era sedantary life-style and drastic changes in food pattern may lead to deaseses like hypertension, dyslipidemia, obesity, diabetes mellitus etc. Hypertension remains one of the most important preventable contributors to disease and death.Today the significance of hypertension as a risk factor for cardiovascular disease is well recognised by every brunch of medical pathies ,untreated hypertension is not only a significant risk factor for the development of cardiovascular morbidity and mortality, but it is also risk factor for renal failour, stroke, blindness and sudden death. According to 2018 guideline of European Society of Cardiology and the European Society of Hypertension is defined as office SBP values >140 mm of Hg and DBP values >90 mm of Hg. Based on office BP, the global prevalence was estimated to be 1.13 billion in 2015.[1]

Hypertension without specific symptoms in its mild and moderate stages cannot be considered as a disease in ayurveda. Ayurveda has clearly described about physiology of blood pressure and the hypertension can be easily understood by assessing *dosa-dushya* involvement that has clearly mentioned in Ayurvedic text. The blood first ejected out of the heart, is then distributed to all parts of the body and thereafter return back to the heart through the blood vessels is termed as '*Sirah*'.[3] As it is known, blood pressure is the lateral pressure exerted by the flow of blood on the walls of arteries. The two component of blood pressure Systolic and diastolic blood pressure. Heart contracts during systole by the electrical impulses generates by SA Node which may relate as function of *Vyana Vata* .*Vyana vata* is also responsible for circulation of *Rasa-Rakta*.[3] Heart rate and the nervous control of blood pressure are controlled by *Pranavata*.[3] Again the diastole is attained when heart muscles relax and blood flowing through the narrow structures of the chambers of heart and arteries where is no active push by heart. Thus diastolic BP can be taken under domain of *Kaphadosa* (mainly *Avalambak kapha*).[3] The auto-rhythmicity of the heart is due to the action potential created by the rapid influx of Na^{+} and Ca^{++} ions and efflux of K^{+} ions across the membrane of the SA node. The involvement of these chemical ions can be taken under the purview of *Pitta*.[3] The blood volume and viscosity can be determined by the quantity and quality of *Rasa* and *Rakta*.[3] The heart itself considered as the site for *Paraoja* and *Sadhak pitta* also *mulasthana* of *rasavahi dhamani*. Thus the *Dosas*, *Dhatus*, *Srotas*, *oja* involved in the regulation blood pressure, abnormality of any of them along with pathological condition like *ama* and *avarana* may leads to hypertension.

In last 3 decades, a lot of concerted efforts have been channelled into researching the local plants with anti-hypertensive therapeutic values.About 75-80% of world population use herbal medicines because of their better acceptability with human body and lesser side effects. The north east India is full of natural resource specially in medicinal and aeromaticplants which are extensively used by the traditional user from time immemorial. *Clerodendrum grandulosum* Lindl.[4] Is one of those traditional herbs used as vagetables by more then 20 tribes of north east region and they claim that low incidence of hypertension and obesity due to regular intake of this herb.[7]After assessing the present condition of anti-hypertensive drug,the present work is taken for the study of *Clerodendrum glandulosum* Lindl in the management of mild to modrate cases of Essential hyprtension. The entire hypothesis of management based on a traditionally used potent antihypertensive herb.

AIM & OBJECTIVE

1. To assess the efficacy of *Clerodendrum glandulosum* Lindl.Inthe management of mild to moderate cases of Essential Hypertention.
2. To find out an effective, low cost and safe remedy to resist the Essential Hypertension.

MATERIALS AND METHODS

The study comprised of 86 patients of Hypertension were registered in OPD & IPD of Kayachikitsa department, Govern ment Ayurvedic College & Hospital,Guwahati-14.

Ethical clearance – Theresearch has been approved by the Instutional Ethical committee. Written consent was taken from all the patients before the trial and study was in accordance with ICH GCP Guidelines.

IEC/17/20-159 Dated 9/5/17
Selection of sample – Randomized Sampling
Type of study – Single blind
Duration of study – 60 days

Selection of Drug and Dose – Dried powder of *Clerod en dr umglandulosumLindl*. 1gm b.d.with lukewarm water morning and evening after light meal.

Description of ClerodendrumcolebrookianumWalp. – *ClerodendrumglandulosumLindl*.belongs to the family Verbenaceae.Globally the species is distributed in Bangladesh, Bhutan,China, India, Indonesia, Malaysia, Myanmar, Nepal, Sri Lanka and vietnum. In India, the species is distributed in Assam, Meghalaya, Arunachal Pradesh and Sikkim at attitudes between 1 to 4000 fta.s.l.[5]The plant grows generally moist and waste places [4]. It is a perennial evergreen shrub and grows upto 1.5-3 m in height.[4] Out of 23 species of *Clerodendrum* reported from India,Arunachal Pradesh has accounted 16 species and one variety.[5] It has been reported that the species is distributed from 500-800 m asl in Lower Subansiri, Papum Pare, and Upper Siang districts ofArunachal Pradesh.Many species of genous *Clerodendrum* occurring in north eastern region have been reported to be useful in treatment of various ailments and diseases.[5]

Fresh leaves of nefafu were collected from the village of North lakhimpur district, Assam. The leaves were identified in Dept. of Botany, Gauhati University. The collected leaves were washed thoroughly and then shade dried, powdered and the dried leaves powder was stored in an air tight container for future use.

***Clerodendrum glandulosum* Lindl**

Pre- treatment observation:
After taking consent of the patient the study was carried out along with the registration and necessary information. After preliminary registration diagnostic medical history was taken according to both Ayurvedic and modern clinical methods.

Study design:
The clinical study was comprises 100 subjects of uncomplicated mild to moderate hypertension were randomly selected from OPD and IPD of Kayachikitsa Deptt. Govt. Ayurvedic College & Hospital Guwahati-14 Assam. Some of these patients were known case of hypertension while some were diagnosed for first time when they come with other complains.At the onset their clinical case history was recorded on special proforma with special reference to their systolic and diastolic blood pressure measurement, diet habits,family history of hypertension, socio-economic status, addiction, occupation,drug history and physical Examination. They were subjected to routine examination of blood and urine.

A. Inclusion criteria
1. Patient in between the age group 20-80 years irrespective of sex.
2. Patients having mild to moderate hypertension without complication.
3. Systolic blood pressure140-180mm of Hg and diastolic blood pressure 90-110mm Hg on at least three office measurement.

B. Exclusion criteria
1. Patients refusal to participate in the study.
2. Patients of severe malignant hypertension (SBP>180mm of Hg and DBP>110mm of Hg
3. Pregnant lady.
4. Other genetic,systemic and rheumatic disease.

C. Laboratory investigations
1. Routine blood
2. Routine urine
3. Total cholesterol
4. ECG

D. Criteria for assessment
The assessment of the trial was done on the basis of following parameters:

- **Subjective** : The subjective assessment was done on the basis of following :

Improvement in the following symptoms of Hypertension
1. Severity of Headache
2. Severity of Dizzinesss / Vertigo
3. Severity of Insomnia
4. Severity of easy fatigability
5. Severity of Dyspnoea.

The above symptoms were graded as below
None 0
Mild 1
Moderate2
Severe4

- **Objective:** The fall of Systolic and Diastolic Blood pressure in every 15 days interval taken as objective parameter. The proper measurement of the systemic arterial pressure by cuff sphygmomanometer is one of the hardcore determinations of blood pressure. In this study all norms applied for measuring proper blood pressure.

E. Methods of treatment :
Clinical study: An open non comparataive clinical evaluation was done by inducing a dry powder of *Clerodendrum glandulosum* Lindl.

Dose and Duration: 1 gm in dry powder form twice daily wth lukewarm water for 60 days.

F. Assessment &Follw Up – The assessment of the patient was done at the interval of 15 days.

G. Statistical Analysis :
Total 100 numbers of patients registered. 14 patients have dropped out and 86 patients have been taken for the study. Mean, Standard deviation, Standard error and Z values are are calculated and finally 'p' values are observed to know statistically significant or not.

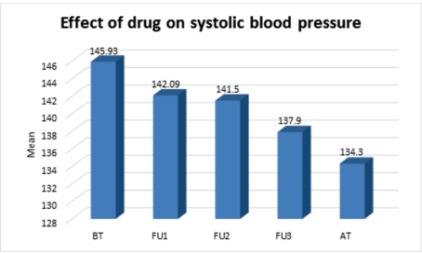
OBSERVATION AND RESULT:
Out of 86 patients maximum patients i.e.59.30% was male and majority i.e.39.55% belonged to age group of 51-60 years. Most of the patients were Hindu i.e.72.09%,majority of i.e.32.55% was service men and 44.18% was of poor socio-economic status. Majority i.e.74.41% were married and 73.25% were of urban habitate.36.04% had diagnosed within 1 year 12.79% were diagnosed before 5 years. 40.69% were without medication and 34.88% were irregular medication.43.02% patients have no any family history of hypertension. 96.51% were non-vegetarian,maximum patients addicted to tea or coffee and betal nut and 39.52% were with mild physical activity.

59.3% patients have Insomnia,66,2% have Dizziness,44.1% have headache.47.6% have Dyspnoea and 68.6% have Easy fatigability during first clinical examination.

a. Effect of drug on systolic blood pressure

The initial mean + SD of Systolic blood pressure was 145.93 + 10.4 was reduced to 142 + 10.3 after 15 days,then after 30 days it was reduced to 141.5 + 8.8, after 45 days it was 137.9 + 6.8 and after 60 days reduced to 134.30 + 9.0. The reduction of systolic blood pressure after 15 days is statistically significant and after 30 days, 45 days & 60 days is statistically highly significant. It implies that the effect of trial drug on systolic blood pressure is highly significant.

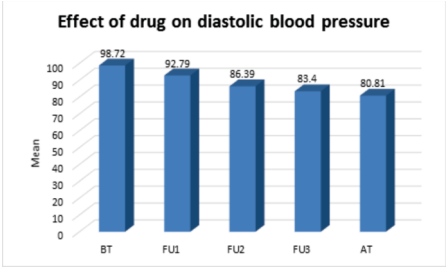
N=86	BT	FU1	BT-FU1	FU2	BT-FU2	FU3	BT-FU3	AT	BT-AT
Mean	145.93	142.09		141.5		137.9		134.30	
SD	10.4	10.3		8.8		6.8		9.0	
SE			1.5		1.4		1.3		1.48
Zvalue			2.56		3.16		6.17		7.85
Pvalue			<0.01		<0.01		<0.001		<0.001
Remarks			Significant		Significant		Highly Significant		Highly Significant



b. Effect of drug on diastolic blood pressure

The initial mean + SD of Diastolic blood pressure was 98.72 + 5.69 reduced to 92.79 + 5.17 after 15 days, then after 30 days it was reduced to 86.39 + 5.66, after 45 days reduced to 83.4 + 4.41 and after 60 days it was reduced to 80.81 + 3.97 . The reduction of diastolic blood pressure after 15 days,30 days,45 days and 60 days are statistically highly significant. It implies that the effect of trial drug on diastolic blood pressure is highly significant.

N=86	BT	FU1	BT-FU1	FU2	BT-FU2	FU3	BT-FU3	AT	BT-AT
Mean	98.72	92.79		86.39		83.4		80.81	
SD	5.69	5.17		5.66		4.41		3.97	
SE			0.82		0.86		0.77		0.74
Zvalue			7.23		14.33		19.89		24.2
Pvalue			<0.001		<0.001		<0.001		<0.001
Remarks			Highly significant		Highly significant		Highly significant		Highly significant



c. Effect of drug on Insomnia

The initial mean + SD of symptom Insomnia was 0.76 + 0.18 reduced to 0.28 + 0.38 after 60 days which implies effect of trial drug statistically significant.

d. Effect of drug on Dizziness

The initial mean + SD of symptom Dizziness was 0.81 + 0.46 reduced to 0.10+0.29 after 60 days which implies effect of of trial drug statistically highly significant.

e. Effect of drug on Headache

The initial mean + SD of symptom Headache was 0.62 + 0.69 reduced to 0.22 + 0.45 after 60 days which implies effect of trial drug statistically significant.

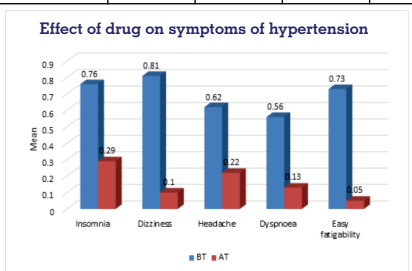
f. Effect of drug on Dyspnoea

The initial mean + SD of symptom Dyspnoea was 0.56 + 0.51 reduced to 0.13 + 0.35 after 60 days which implies effect of trial drugstatistically significant.

g. Effect of drug on Easy fatigability

The initial mean + SD of Easy fatigability was 0.73 + 0.35 reduced 0.05 + 0.23 which implies the effect of trial drug is statistically highly significant.

N-86	$\bar{X}$ BT	$\bar{X}$FU1	$\bar{X}$FU2	$\bar{X}$Fu3	$\bar{X}$ AT	SD		SE (BT-AT)	Z value	P value	Remarks
						BT	AT				
Insomnia	0.76	0.58	0.50	0.48	0.29	0.18	0.38	0.17	2.76	<0.01	Significant
Dizziness	0.81	0.62	0.47	0.40	0.10	0.46	0.29	0.05	14.2	<0.001	Highly significant
Headache	0.62	0.38	0.33	0.18	0.22	0.69	0.45	0.08	5.0	<0.001	Significant
Dyspnoea	0.56	0.47	0.39	0.25	0.13	0.51	0.35	0.05	7.1	0.001	Significant
Easy fatigability	0.73	0.60	0.51	0.33	0.05	0.35	0.23	0.04	17.0	<0.001	Highly significant



DISCUSSION AND CONCLUSION

- Undetected & uncontrolled hypertension that increases the cardoiovascular risk is a major contributor of stroke worldwide in now a days. Awareness programes are initial and vital step toward optimal control.
- Herbal drugs are always beneficial for management of diseases and promotion good health. Assamese tribal and non tribal people use some antihypertensive herbs in their day to day life like *Clerodendrum colebrookianum*, *Allium sativum*, *Terminalia arjuna* etc.

- The present clinical study shows that *Clerodendrum glandulosum* Lindl. is very effective in the management of essential hypertension. No untoward effect was noted during treatment and follow up period and patient satisfaction also noted. Though this study is a preliminary study as a part of the educational research programme with limited number of patients in a fix stipulated time. In order to establish the antihypertensive effect of this drug, a broad spectrum clinical and experimental study is required with the application of new technology to establish its effect in view of modern and scientific approach.

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