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Original Research Paper

Ayurveda

EFFICACY OF A TRADITIONALLY USED HERB NEPHAPHU IN HYPERTENSION

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ABSTRACT

Hypertension is a major health problem that affects approximately 29% of the adult population worldwide. It is a major risk factor for cardio-vascular disease, contributing greatly to morbidity and mortality from stroke, myocardial infarction, end stage renal disease and congestive heart failure. Indian people traditionally consuming different herbs for different ainments for prevention and cure of diseases. In North eastern region people use a herbs traditionally called nephaphu (clerodemdrumcolibrookinum) as vegetables since long time in various diseases specially in hypertension and they believe that due to that herb they are not suffering from hypertension. A clinical study was conducted among 60 cases of hypertension among than 20 cases were newly diagnosed case of hypertension, 20 cases were hypertension with or without disturbance of lipid profile, 20 cases were chronic hypertension under the modern medication (amlopidine) were randomly selected from OPD and IPD of Govt. Ayurvedic College & Hospital, Jalukbari, Guwahati- 14, Assam. The data should significant result in all the three groups in the management of hypertension and complication were found during and after the clinical study.

Indian people traditionally consuming different herbs for different ainments for prevention and cure of diseases. In North Eastern region in Manipur, Mizoram,Meghalaya,Arunachal Pradesh and in some parts of Assam, people use a herb traditionally called Nephaphu(clerodendrumcolibrookinum) as vegetables since long time in various diseases specially in hypertension,and they believe that due to that herb they are not suffering from hypertension. Multiple study in vitro shows that it has hypolipidaemic effect, but still no any clinical study paper found that it is effective in human also. So keeping that view in my work, I have evaluated this traditional herb in hypertensive patient.

KEYWORDS : Hypertension, Cerebrovascular Diseases, Myocardial Infarction, Nephaphu

Aims & Objective:

To assesse the efficacy of the drug nephaphu (clerodendrumcolibrookinum) in hypertensive patient.

Materials & Methods:

The study comprised of 60 patients of hypertension were registered in OPD and IPD of Govt. Ayurvedic College & Hospital, Jalukbari, Guwahati- 14.

Ethical clearance:

The research has been approved by the institutional ethical committee. Written consent was taken from all the patients before the trial and study was in accordance with ICAGCP guidelines. IEC/17/20-150 dated 09-05-2017.

Selection of sample: Randomized sampling.
Duration: 45 Days.
Selection of drugs and dose:
Dried powder of nephaphu (clerondendrumcolibrookinum) 2gm b.d. with lukewarm water.

Description of clerondendrumcolibrookinum:

*Clerodendrumcolebrookianum*Walp. (Synonymous to *Clerodendrumglandulosum*Coleb.), belongs to the family Verbenaceae. Globally the species is distributed in Bangladesh, Bhutan, China, India, Indonesia, Malaysia, Myanmar, Nepal, Sri Lanka and Vietnam. In India, the species is distributed in the states of Assam, Meghalaya and Sikkim at altitudes between 1 to 4000 ft.. The species occupy every possible habitat such as roadsides, forest edges, moist, shady places and amidst bushes. It is a perennial shrub and has been reported to be endemic to north eastern region of India. Out of the 23 species of *Clerodendrum*reported from India, Arunachal Pradesh has accounted 16 species and 1 variety. It has been reported that the species is distributed from 500 to 800 m in Lower Subansiri, Papum Pare and Upper Siang districts of Arunachal Pradesh.

Pre-treatment observation:

After taking consent of the patients 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:

- All the patient were randomly selected from OPD and IPD Govt. Ayurvedic College & Hospital, Guwahati.
- Total 200 nos. of hypertensive patients were registered for study.
- Among them 60 patients were selected for clinical trial which is divided into the following three groups –

Group-A: 20 Patients of newly diagnosed case of hypertension.

Group-B: 20 patients of hypertension with or without disturbance of lipid profile.

Group-C: 20 patients of chronic Hypertension undermodern medication. (Amlodipine)

- All the selected patients were undergone follow up on the basis of subjective and objective parameters before and after treatment.

INCLUSION CRITERIA:

1. All the patients of Hypertension were selected for Aetiopathological study.
2. For clinical study, Patient having systolic blood pressure >140 mm of Hg and diastolic blood pressure >90 mm of Hg were included.
3. Age group:18 to 60 years, which include

- Newly diagnosed case of Hypertension,
- Hypertension with or without the disturbance of lipid profile and
- Chronic hypertension under modern medication (Amlodipine).

EXCLUSION CRITERIA:

1. There is no any exclusion critaria for aetiopathological study.
2. For clinical study- Pregnant lady, Complicated hypertensive cases eg: nephropathy and left ventricular hypertrophy ,heart block, congestive heart failure, coronary artery disease were excluded.
3. Systolic blood pressure >160mm of Hg and diastolic blood pressure >100mm of Hg were excluded.

DIAGNOSIS CRITERIA:

Diagnosis was done on the basis of clinical and laboratorical parameters.

CRITERIA FOR WITHDRAWL:

a) Elevation of blood pressure during the course of trial period.
b) Discontinuation of the treatment during trial period.
c) Any other serious complications requiring changes in treatment.

ROUTINE EXAMINATION ASSESSMENT & FOLLOW UP:

- All selected patients were selected as per specially designed proforma to diagnose hypertension as per Ayurveda.
- Routine laboratory investigation was done for all selected patients at the time of registration and clinical trial group patients. Investigations were done before and after treatment.
- Trial group patients were taken in 3 consecutive follow up in 15 days,30 days and 45 days of interval.
- **Trial methodology**: Modern methodology for trial and statistics design suitably be adopted for the present study.
- **Simple random sampling**: The selection of patient for the study were done in randomized design.
- The patient were selected from OPD, IPD of Govt. Ayurvedic College & Hospital, Guwahati

LABORATORY INVESTIGATIONS:

LIPID PROFILE:

Cholesterol.	150- 200 mg /dl
Triglycerides.	40- 140 mg/dl
HDL.	35- 175 mg/dl
LDL.	65- 170 mg/dl
VLDL.	5- 35 mg/ dl

Methods of treatments:

Clinical study:

An open non- comparative clinical evaluation was done by inducing a dried powder of clerodendrumcolibrookinum.

Dose and duration:

2gm twice daily with lukewarm for 45 days.

Assessment and follow-up:

The assessment of the patient was done of the interval 15 days.

OBSERVATION AND RESULTS

The study has been divided into Demographic and clinical profile. Total 200 patients were registered for the entire study. Among them 60 patients were selected for the clinical trial to see the efficacy of the traditionally used drug Nephaphu (ClerodendrumColibrookinum). These 60 patients it was divided into three groups namely:

A. Newly diagnosed case of Hypertension
B. Hypertension with or without the disturbance of lipid profile.
C. Chronic Hypertension under modern medication (Amlodipine)

EFFECT OF TRIAL DRUG ON SYSTOLIC BLOOD PRESSURE

PAIRED t- TEST

GROUP- A

Before treatment &Follow- up- 1

$\bar{X}_{BT}$	$\bar{X}_{Fu1}$	SD_{BT}	SD_{FU1}	SEM	t	p	Remarks
141.00	135.8	8.52	8.28	1.1	4.6	0.0002	Highly significant

Before treatment &Follow- up- 2

$\bar{X}_{BT}$	$\bar{X}_{Fu2}$	SD_{BT}	SD_{FU2}	SEM	t	p	Remarks
141.00	135.8	8.52	8.28	1.1	4.6	0.0002	Highly significant

Before treatment& after treatment (follow- up- 3)

$\bar{X}_{BT}$	$\bar{X}_{AT}$	SD_{BT}	SD_{AT}	SEM	t	p	Remarks
141.00	133.00	8.52	5.72	1.367	5.8	<0.0001	Highly significant

The outcome of the statistical analysis shows that the mean values of SBP in Group A before treatment was 141 mm of Hg. It decreased to 135.8 mm of Hg after 15 days of treatment, it remains same after 30 days of treatment and the reduced to 133 mm of Hg after 45 days of treatment.

The test of significant i.e. t19= 5.8 shows the effect of trial drug is highly significant with p value <0.0001.

Group B

Before treatment &Follow- up- 1

$\bar{X}_{BT}$	$\bar{X}_{FU1}$	SD_{BT}	SD_{FU1}	SEM	t	p	Remarks
146.5	140.00	10.89	7.25	1.313	4.9	<0.0001	Highly significant

Before treatment &Follow- up- 2

$\bar{X}_{BT}$	$\bar{X}_{FU2}$	SD_{BT}	SD_{FU2}	SEM	t	p	Remarks
146.5	140.00	10.89	7.25	1.313	4.9	<0.0001	Highly significant

Before treatment & after treatment (follow- up- 3)

$\bar{X}_{BT}$	$\bar{X}_{AT}$	SD_{BT}	SD_{AT}	SEM	t	p	Remarks
146.5	137.50	10.89	7.86	1.60	5.6	<0.0001	Highly significant

The test of significant i.e. t19= 5.5 shows the effect of trial drug is highly significant with p value <0.0001.

The outcome of the statistical analysis shows that the mean values of SBP in Group A before treatment was 146.5 mm of Hg. It decreased to 140 mm of Hg after 15 days of treatment, it remains same i.e. 140 mm of Hg after 30 days of treatment and the reduced to 137.5 mm of Hg after 45 days of treatment.
The test of significant i.e. t19= 5.6 shows the effect of trial drug is highly significant with p value <0.0001.

Group- C

Before treatment &Follow- up- 1

$\bar{X}_{BT}$	$\bar{X}_{FU1}$	SD_{BT}	SD_{FU1}	SEM	t	p	Remarks
142.5	137.9	8.51	6.14	1.33	3.4	0.002	Highly significant

Before treatment &Follow- up- 2

$\bar{X}_{BT}$	$\bar{X}_{FU2}$	SD_{BT}	SD_{FU2}	SEM	t	p	Remarks
142.5	135.5	8.51	6.86	1.227	5.4	<0.0001	Highly significant

Before treatment & after treatment (follow- up- 3)

$\bar{X}_{BT}$	$\bar{X}_{AT}$	SD_{BT}	SD_{AT}	SEM	t	p	Remarks
142.5	133	8.51	6.57	1.535	6.1	<0.0001	Highly significant

The outcome of the statistical analysis shows that the mean values of SBP in Group A before treatment was 142.5 mm of

Hg. It reduced to 137.9 mm of Hg after 15 days of treatment, it reduced to 135.5 mmHg after 30 days of treatment and then reduced to 133 mm of Hg after 45 days of treatment.

The test of significant i.e. t19= 6.1 shows the effect of trial drug is highly significant with p value <0.0001.

The effect of trail drug on diastolic blood pressure-Diastolic B.P.

GROUP A

Before treatment &Follow- up- 1

$\bar{X}_{BT}$	$\bar{X}_{Fu1}$	SD_{BT}	SD_{FU1}	SEM	t	p	Remarks
92	88.00	6.16	6.05	1.04	3.8	0.001	Highly significant

Before treatment &Follow- up- 2

$\bar{X}_{BT}$	$\bar{X}_{Fu2}$	SD_{BT}	SD_{FU2}	SEM	t	p	Remarks
92	88.00	6.16	6.05	1.04	3.8	0.001	Highly significant

Before treatment & after treatment (follow- up- 3)

$\bar{X}_{BT}$	$\bar{X}_{AT}$	SD_{BT}	SD_{AT}	SEM	t	p	Remarks
92	80.4	6.16	8.77	1.928	6.0	<0.0001	Highly significant

The outcome of the statistical analysis shows that the mean values of DBP in Group A before treatment was 92 mm of Hg It decreased to 88 mm of Hg after 15 days of treatment, it remains same i.e. 88 mm of Hg after 30 days of treatment and then reduced to 80.4 mm of Hg after 45 days of treatment.

The test of significant i.e. t19= 6.0 shows the effect of trial drug is highly significant with p value <0.0001.

Group – B

Before treatment &Follow- up- 1

$\bar{X}_{BT}$	$\bar{X}_{Fu1}$	SD_{BT}	SD_{FU1}	SEM	t	p	Remarks
93.5	86.5	6.71	6.71	1.79	3.9	0.0009	Highly significant

Before treatment &Follow- up- 2

$\bar{X}_{BT}$	$\bar{X}_{Fu2}$	SD_{BT}	SD_{FU2}	SEM	t	p	Remarks
93.5	85.5	6.71	6.05	1.71	4.6	0.0002	Highly significant

Before treatment & after treatment (follow- up- 3)

$\bar{X}_{BT}$	$\bar{X}_{AT}$	SD_{BT}	SD_{AT}	SEM	t	p	Remarks
93.5	84	6.71	6.81	1.846	5.146	<0.0001	Highly significant

The outcome of the statistical analysis shows that the mean values of DBP in Group A before treatment was 93.5 mm of Hg It decreased to 86.50 mm of Hg after 15 days of treatment, it decreased to 85.50 mm Hg after 30 days of treatment and then reduced to 84 mm of Hg after 45 days of treatment.

The test of significant i.e. t19= 5.146 shows the effect of trial drug is highly significant with p value <0.0001.

Group – C

Before treatment &Follow- up- 1

$\bar{X}_{BT}$	$\bar{X}_{Fu1}$	SD_{BT}	SD_{FU1}	SEM	t	p	Remarks
90.5	86.5	6.05	6.71	1.7	3.9	0.0009	Highly significant

Before treatment &Follow- up- 2

$\bar{X}_{BT}$	$\bar{X}_{Fu2}$	SD_{BT}	SD_{FU2}	SEM	t	p	Remarks
90.5	86.5	6.05	6.71	1.7	3.9	0.0009	Highly significant

Before treatment & after treatment (follow- up- 3)

$\bar{X}_{BT}$	$\bar{X}_{AT}$	SD_{BT}	SD_{AT}	SEM	t	p	Remarks
90.5	81.9	6.05	9.98	2.0	4.1	0.0005	significant

The outcome of the statistical analysis shows that the mean values of DBP in Group A before treatment was 90.5 mm of Hg It decreased to 86.5 mm of Hg after 15 days of treatment, it remains same i.e. 86.5 mm Hg after 30 days of treatment and then reduced to 81.9 mm of Hg after 45 days of treatment.

The test of significant i.e. t19= 4.1 shows the effect of trial drug is highly significant with p value =0.0005.

SUBJECTIVE PERAMETERS

Effect of drugs onGIDDINESS

Paired t- test Group A

Before treatment &Follow- up- 1

$\bar{X}_{BT}$	$\bar{X}_{Fu1}$	SD_{BT}	SD_{FU1}	SEM	t	p	Remarks
1.1	0.95	0.85	0.76	0.082	1.8	0.08	Not quite significant

Before treatment &Follow- up- 2

$\bar{X}_{BT}$	$\bar{X}_{Fu2}$	SD_{BT}	SD_{FU2}	SEM	t	p	Remarks
1.1	0.4	0.85	0.50	0.128	5.4	<0.0001	Highly significant

Before treatment & after treatment (follow- up- 3)

$\bar{X}_{BT}$	$\bar{X}_{AT}$	SD_{BT}	SD_{AT}	SEM	t	p	Remarks
1.1	0.3	0.85	0.47	0.138	5.8	<0.0001	Highly significant

The outcome of the statistical analysis shows that the mean value of Giddiness in Group A before treatment was 1.1 this reduced to 0.95 after 15 days of treatment, 0.40 after 30 days of treatment, then 0.30 after 45 days of treatment.

The test of significant i.e. t13= 5.8 shows the effect of trial drug is highly significant with p value <0.001.

t_{13} = 5.8, p <0.001, hence result is highly significant. It implies that the effect of drug in Group- A is statically highly significant means it shows that in newly diagnosed case of hypertension is reduced by trial drug.

GROUP-B

GIDDINESS

Before treatment &Follow- up- 1

$\bar{X}_{BT}$	$\bar{X}_{Fu1}$	SD_{BT}	SD_{FU1}	SEM	t	p	Remarks
1.15	0.95	0.93	0.83	0.09	2.1	0.04	significant

Before treatment &Follow- up- 2

$\bar{X}_{BT}$	$\bar{X}_{Fu2}$	SD_{BT}	SD_{FU2}	SEM	t	p	Remarks
1.15	0.45	0.93	0.51	0.12	5.4	<0.0001	Highly significant

Before treatment & after treatment (follow- up- 3)

$\bar{X}_{BT}$	$\bar{X}_{AT}$	SD_{BT}	SD_{AT}	SEM	t	p	Remarks
1.15	0.3	0.93	0.47	0.167	5.1	<0.0001	Highly significant

The outcome of the statistical analysis shows that the mean value of Giddiness in Group B before treatment was 1.15 this reduced to 0.95after 15 days of treatment, 0.45 after 30 days of treatment, then 0.30 after 45 days of treatment.

The test of significant i.e. t12= 6.4. Shows the effect of trial drug is highly significant with p value <0.0001.

T_{12} = 6.4, p <0.0001, hence result is highly significant. It implies that the effect of drug in Group- B is statically highly significant means it shows that in case of hypertension with or without lipid profile is reduced by trial drug.

GROUP-C

Before treatment &Follow- up- 1

$\bar{X}_{BT}$	$\bar{X}_{AT}$	SD_{BT}	SD_{AT}	SEM	t	p	Remarks
1.20	1.00	0.89	0.73	0.092	2.1	0.04	significant

Before treatment &Follow- up- 2

$\bar{X}_{BT}$	$\bar{X}_{AT}$	SD_{BT}	SD_{AT}	SEM	t	p	Remarks
1.20	1.00	0.89	0.73	0.092	2.1	0.04	significant

Before treatment and after treatment (follow- up- 3)

$\bar{X}_{BT}$	$\bar{X}_{AT}$	SD_{BT}	SD_{AT}	SEM	t	p	Remarks
1.20	0.50	0.89	0.69	0.128	5.4	<0.001	significant

The outcome of the statistical analysis shows that the mean value of Giddiness in Group C before treatment was 1.20 this reduced to 1.00 after 15 days of treatment, It remains same.i.e.1.00 after 30 days of treatment,then it reduced to 0.50 after 45 days of treatment.

The test of significant i.e. t.= 5.4. Shows the effect of trial drug is highly significant with p value = <0.0001.

t= 5.4, p = <0.0001, hence result is highly significant. It implies that the effect of drug in Group- c is statistically highly significant, means it shows that in case of hypertension with amlodipine is reduced by trial drug.

PAIRED t- TEST

EFFECT OF DRUGS ON HEADACHE : GROUP A:

Before treatment &Follow- up- 1

$\bar{X}_{BT}$	$\bar{X}_{Fu1}$	SD_{BT}	SD_{FU1}	SEM	t	p	Remarks
1.35	1.20	0.93	0.83	0.08	1.8	0.08	Not quite significant

Before treatment &Follow- up- 2

$\bar{X}_{BT}$	$\bar{X}_{Fu2}$	SD_{BT}	SD_{FU2}	SEM	t	p	Remarks
1.35	0.60	0.93	0.60	0.099	7.5	<0.0001	Highly significant

Before treatment & after treatment (follow- up- 3)

$\bar{X}_{BT}$	$\bar{X}_{AT}$	SD_{BT}	SD_{AT}	SEM	t	p	Remarks
1.35	0.50	0.93	0.51	0.131	6.4	<0.0001	Highly significant

The outcome of the statistical analysis shows that the mean value of Headache in Group A before treatment was 1.35 this reduced to 1.20 after 15 days of treatment, 0.60 after 30 days of treatment, it reduced to 0.50 after 45 days of treatment.

The test of significant i.e. t9= 6.4 shows the effect of trial drug is highly significant with p value <0.001.

t_9 = 6.4, p <0.001, hence result is highly significant. It implies that the effect of drug in Group- A is statically highly significant means it shows that in newly diagnosed case of hypertension is reduced by trial drug.

GROUP-B

HEADACHE

Effect of drugs on Headache:

Before treatment &Follow- up- 1

$\bar{X}_{BT}$	$\bar{X}_{Fu1}$	SD_{BT}	SD_{FU1}	SEM	t	p	Remarks
1.10	0.85	0.97	0.81	0.099	2.5	0.02	significant

Before treatment &Follow- up- 2

$\bar{X}_{BT}$	$\bar{X}_{Fu2}$	SD_{BT}	SD_{FU2}	SEM	t	p	Remarks
1.10	0.50	0.97	0.51	0.112	5.3	<0.0001	Highly Significant

Before treatment & after treatment (follow- up- 3)

$\bar{X}_{BT}$	$\bar{X}_{AT}$	SD_{BT}	SD_{AT}	SEM	t	p	Remarks
1.10	0.30	0.97	0.47	0.172	4.6	0.0002	Highly significant

The outcome of the statistical analysis shows that the mean value of Headache in Group B before treatment was 1.10 this reduced to 0.85 after 15 days of treatment, 0.50 after 30 days of treatment, it reduced to 0.30 after 45 days of treatment.

The test of significant i.e. t11= 4.6. Shows the effect of trial drug is highly significant with p value =0.0002.

t_{12} = 4.6, p =0.0002, hence result is highly significant. It implies that the effect of drug in Group- B is statically highly significant means it shows that in case of hypertension with with or without disturbance of lipid profile is reduced by trial drug.

GROUP-C

EFFECT OF DRUGS ON HEADACHE

Before treatment &Follow- up- 1

$\bar{X}_{BT}$	$\bar{X}_{Fu1}$	SD_{BT}	SD_{FU1}	SEM	t	p	Remarks
1.25	1.00	0.79	0.73	0.09	2.5	0.02	significant

Before treatment &Follow- up- 2

$\bar{X}_{BT}$	$\bar{X}_{Fu2}$	SD_{BT}	SD_{FU2}	SEM	t	p	Remarks
1.25	1.00	0.79	0.73	0.09	2.5	0.02	significant

Before treatment & after treatment(follow- up- 3)

$\bar{X}_{BT}$	$\bar{X}_{AT}$	SD_{BT}	SD_{AT}	SEM	t	p	Remarks
1.25	0.60	0.79	0.60	0.109	5.9	<0.0001	Highly significant

The outcome of the statistical analysis shows that the mean value of Headache in Group C before treatment was 1.25 this reduced to 1.00 after 15 days of treatment, it remain same 1.00 after 30 days of treatment, it reduced to 0.60 after 45 days of treatment.

The test of significant i.e. t15= 8.06. Shows the effect of trial drug is highly significant with p value <0.0001.

T_{15} = 8.06, p <0.0001 hence result is highly significant. It implies that the effect of drug in Group- C is statistically highly significant means it shows that in case of hypertension under amlodipine is reduced by trial drug.

GROUP-A

LACK OF SLEEP

Effect of drugs on lack of sleep

Before treatment &Follow- up- 1

$\bar{X}_{BT}$	$\bar{X}_{Fu1}$	SD_{BT}	SD_{FU1}	SEM	t	p	Remarks
0.70	0.40	1.03	0.40	0.128	2.3	0.02	significant

Before treatment &Follow- up- 2

$\bar{X}_{BT}$	$\bar{X}_{Fu2}$	SD_{BT}	SD_{FU2}	SEM	t	p	Remarks
0.70	0.20	1.03	0.41	0.17	2.9	0.008	Highly Significant

Before treatment & after treatment (follow- up- 3)

$\bar{X}_{BT}$	$\bar{X}_{AT}$	SD_{BT}	SD_{AT}	SEM	t	p	Remarks
0.70	0.04	1.03	0.22	0.221	2.9	0.0084	Highly significant

The outcome of the statistical analysis shows that the mean value of Lack of sleep in Group A before treatment was 0.70 this reduced to 0.40 after 15 days of treatment, it decreased to 0.20 after 30 days of treatment, it reduced to 0.04 after 45 days of treatment.

The test of significant i.e. t6= 2.9 shows the effect of trial drug is highly significant with p value =0.0008.

t_6 = 2.9, p =0.0008, hence result is highly significant. It implies that the effect of drug in Group- A is statically highly significant means it shows that in newly diagnosed case of hypertension is reduced by trial drug.

GROUP-B

LACK OF SLEEP

Effect of drugs on lack of sleep

Before treatment &Follow- up- 1

$\bar{X}_{BT}$	$\bar{X}_{Fu1}$	SD_{BT}	SD_{FU1}	SEM	t	p	Remarks
0.95	0.75	1.05	0.91	0.092	2.1	0.04	significant

Before treatment &Follow- up- 2

$\bar{X}_{BT}$	$\bar{X}_{Fu2}$	SD_{BT}	SD_{FU2}	SEM	t	p	Remarks
0.95	0.40	1.05	0.60	0.135	4.0	0.0007	Not significant

Before treatment & after treatment (follow- up- 3)

$\bar{X}_{BT}$	$\bar{X}_{AT}$	SD_{BT}	SD_{AT}	SEM	t	p	Remarks
0.95	0.25	1.05	0.44	0.179	3.9	0.0009	Highly significant

The outcome of the statistical analysis shows that the mean value of Lack of sleep in Group B before treatment was 0.95 this reduced to 0.75 after 15 days of treatment, it decreased to 0.40 after 30 days of treatment, it reduced to 0.25 after 45 days of treatment.

The test of significant i.e. t9= 3.9. Shows the effect of trial drug is highly significant with p value =0.0009.

T_9 = 3.9, p =0.0009, hence result is highly significant. It implies that the effect of drug in Group- B is statically highly significant means it shows that in case of hypertension with or without disturbance of lipid profile is reduced by trial drug.

GROUP-C
EFFECT OF DRUGS ON LACK OF SLEEP

Before treatment &Follow- up- 1

$\bar{X}_{BT}$	$\bar{X}_{Fu1}$	SD_{BT}	SD_{FU1}	SEM	t	p	Remarks
0.70	0.45	0.92	0.69	0.099	2.5	0.02	significant

Before treatment &Follow- up- 2

$\bar{X}_{BT}$	$\bar{X}_{Fu1}$	SD_{BT}	SD_{FU1}	SEM	t	p	Remarks
0.70	0.30	0.55	0.66	0.134	2.9	0.0075	Highly Significant

Before treatment & after treatment (follow- up- 3)

$\bar{X}_{BT}$	$\bar{X}_{AT}$	SD_{BT}	SD_{AT}	SEM	t	p	Remarks
0.70	0.25	0.92	0.55	0.114	3.9	0.0009	significant

The outcome of the statistical analysis shows that the mean value of Lack of sleep in Group C before treatment was 0.70 this reduced to 0.45 after 15 days of treatment, it decreased to 0.30 after 30 days of treatment, it again reduced to 0.25 after 45 days of treatment.

The test of significant i.e. t8= 5.2. Shows the effect of trial drug is highly significant with p value = 0.0007.

t_8 = 5.2, p = 0.0007 hence result is highly significant. It implies that the effect of drug in Group- C is statically highly significant means it shows that in case of hypertension under medication amlodipine is reduced by trial drug.

GROUP-A
FATIGUE

Before treatment &Follow- up- 1

$\bar{X}_{BT}$	$\bar{X}_{Fu1}$	SD_{BT}	SD_{FU1}	SEM	t	p	Remarks
0.70	0.40	1.03	0.40	0.128	2.3	0.02	significant

Before treatment &Follow- up- 2

$\bar{X}_{BT}$	$\bar{X}_{Fu2}$	SD_{BT}	SD_{FU2}	SEM	t	p	Remarks
0.70	0.20	1.03	0.41	0.17	2.9	0.008	Highly Significant

Before treatment & after treatment (follow- up- 3)

$\bar{X}_{BT}$	$\bar{X}_{AT}$	SD_{BT}	SD_{AT}	SEM	t	p	Remarks
0.70	0.04	1.03	0.22	0.221	2.9	0.0084	Highly significant

The outcome of the statistical analysis shows that the mean value of Lack of sleep in Group A before treatment was 0.70 this reduced to 0.40 after 15 days of treatment, it decreased to 0.20 after 30 days of treatment, it reduced to 0.04 after 45 days of treatment.

The test of significant i.e. t6= 2.9 shows the effect of trial drug is highly significant with p value =0.0008.

t_6 = 2.9, p =0.0008, hence result is highly significant. It implies that the effect of drug in Group- A is statically highly significant means it shows that in newly diagnosed case of hypertension is reduced by trial drug.

GROUP-B
FATIGUE

Before treatment &Follow- up- 1

$\bar{X}_{BT}$	$\bar{X}_{Fu1}$	SD_{BT}	SD_{FU1}	SEM	t	p	Remarks
0.95	0.75	1.05	0.91	0.092	2.1	0.04	significant

Before treatment &Follow- up- 2

$\bar{X}_{BT}$	$\bar{X}_{Fu1}$	SD_{BT}	SD_{FU1}	SEM	t	p	Remarks
0.95	0.40	1.05	0.60	0.135	4.0	0.0007	Not significant

Before treatment & after treatment (follow- up- 3)

$\bar{X}_{BT}$	$\bar{X}_{AT}$	SD_{BT}	SD_{AT}	SEM	t	p	Remarks
0.95	0.25	1.05	0.44	0.179	3.9	0.0009	Highly significant

The outcome of the statistical analysis shows that the mean value of Lack of sleep in Group B before treatment was 0.95 this reduced to 0.75 after 15 days of treatment, it decreased to 0.40 after 30 days of treatment, it reduced to 0.25 after 45 days of treatment.

The test of significant i.e. t9= 3.9. Shows the effect of trial drug is highly significant with p value =0.0009.

T_9 = 3.9, p =0.0009, hence result is highly significant. It implies that the effect of drug in Group- B is statically highly significant means it shows that in case of hypertension with or without disturbance of lipid profile is reduced by trial drug.

GROUP-C
EFFECT OF DRUGS ON FATIGUE

Before treatment &Follow- up- 1

$\bar{X}_{BT}$	$\bar{X}_{Fu1}$	SD_{BT}	SD_{FU1}	SEM	t	p	Remarks
0.70	0.45	0.92	0.69	0.099	2.5	0.02	significant

Before treatment &Follow- up- 2

$\bar{X}_{BT}$	$\bar{X}_{Fu2}$	SD_{BT}	SD_{FU2}	SEM	t	p	Remarks
0.70	0.30	0.55	0.66	0.134	2.9	0.0075	Highly Significant

Before treatment & after treatment (follow- up- 3)

$\bar{X}_{BT}$	$\bar{X}_{AT}$	SD_{BT}	SD_{AT}	SEM	t	p	Remarks
0.70	0.25	0.92	0.55	0.114	3.9	0.0009	significant

The outcome of the statistical analysis shows that the mean value of Lack of sleep in Group C before treatment was 0.70 this reduced to 0.45 after 15 days of treatment, it decreased to 0.30 after 30 days of treatment, it again reduced to 0.25 after 45 days of treatment.

The test of significant i.e. t8= 5.2. Shows the effect of trial drug is highly significant with p value = 0.0007.

t_8 = 5.2, p = 0.0007 hence result is highly significant. It implies that the effect of drug in Group- C is statically highly significant means it shows that in case of hypertension umder medication amlodipine is reduced by trial drug.

OBJECTIVE PARAMETERS

Group- A paired T- test

Cholesterol

$\bar{X}_{BT}$	$\bar{X}_{AT}$	SD_{BT}	SD_{AT}	SEM	t	p	Remarks
152.78	141.41	11.2	7.3	3.7	3.4	0.0091	Highly significant

The test of significant i.e. t19= 3.4 shows the effect of trial drug is highly significant with p value <0.0001.

Group- B paired T- test

Cholesterol

$\bar{X}_{BT}$	$\bar{X}_{AT}$	SD_{BT}	SD_{AT}	SEM	t	p	Remarks
163.4	141.7	13.1	11.1	4.7	4.6	0.0012	significant

The test of significant i.e. t19= 4.6 shows the effect of trial drug is highly significant with p value <0.0001.

Group- C
Paired T- test
Cholesterol

$\bar{X}_{BT}$	$\bar{X}_{AT}$	SD_{BT}	SD_{AT}	SEM	t	p	Remarks
153.4	141.8	19.89	15.89	3.6	3.1	0.0115	significant

The test of significant i.e. t19= 3.1 shows the effect of trial drug is highly significant with p value <0.0001.

PAIRED T- TEST
TRIGLYCERIDE
Group- A

$\bar{X}_{BT}$	$\bar{X}_{AT}$	SD_{BT}	SD_{AT}	SEM	t	p	Remarks
137.4	140.4	8.9	12	3.9	0.74	0.47	Not significant

The test of significant i.e. t19= 0.74, p > 0.01 hence it is a statically in significant it implied that the effect of drug on triglyceride in group- C not satisfactory.

PAIRED T- TEST
TRIGLYCERIDE
Group- B

$\bar{X}_{BT}$	$\bar{X}_{AT}$	SD_{BT}	SD_{AT}	SEM	t	p	Remarks
255.5	259.6	16.47	11.33	2.9	0.6	0.55	Not significant

The test of significant i.e. t19= 0.6, p > 0.01 hence it is a statically in significant it implied that the effect of drug on triglyceride in group- C not satisfactory.

PAIRED T- TEST
TRIGLYCERIDE
Group- C

$\bar{X}_{BT}$	$\bar{X}_{AT}$	SD_{BT}	SD_{AT}	SEM	t	p	Remarks
255.5	142.4	8.9	12	3.9	0.74	0.47	Not significant

The test of significant i.e. t19= 0.74, p > 0.01 hence it is a statically in significant it implied that the effect of drug on triglyceride in group- C not satisfactory.

HDL
Group- A

$\bar{X}_{BT}$	$\bar{X}_{AT}$	SD_{BT}	SD_{AT}	SEM	t	p	Remarks
46.8	44.2	8	7.9	4.19	0.6	0.54	Not significant

The test of significant i.e. t19= 0.6, p > 0.01 hence it is a statically in significant it implied that the effect of drug on HDL in group- A not satisfactory.

Group- B

$\bar{X}_{BT}$	$\bar{X}_{AT}$	SD_{BT}	SD_{AT}	SEM	t	p	Remarks
48	44.4	6.16	5.14	2.8	1.2	0.24	Not significant

The test of significant i.e. t19= 1.2, p > 0.01 hence it is a statically in significant it implied that the effect of drug on HDL in group- B not satisfactory.

Group- C

$\bar{X}_{BT}$	$\bar{X}_{AT}$	SD_{BT}	SD_{AT}	SEM	t	p	Remarks
44	40.4	6.16	5.14	2.8	1.23	0.24	Not significant

The test of significant i.e. t19= 1.23, p > 0.01 hence it is a statically in significant it implied that the effect of drug on HDL in group- C not satisfactory.

LDL
Group- A

$\bar{X}_{BT}$	$\bar{X}_{AT}$	SD_{BT}	SD_{AT}	SEM	t	p	Remarks
56	52.4	6.16	5.14	2.88	1.2	0.246	Not significant

The test of significant i.e. t19= 1.2, p > 0.01 hence it is a statically in significant it implied that the effect of drug on LDL in group- A not satisfactory.

Group- B

$\bar{X}_{BT}$	$\bar{X}_{AT}$	SD_{BT}	SD_{AT}	SEM	t	p	Remarks
66	63.4	6.16	4.3	2.0	1.2	0.24	Not significant

The test of significant i.e. t19= 1.2, p > 0.01 hence it is a statically in significant it implied that the effect of drug on LDL in group- C not satisfactory.

Group- C

$\bar{X}_{BT}$	$\bar{X}_{AT}$	SD_{BT}	SD_{AT}	SEM	t	p	Remarks
50	46.4	6.16	5.14	2.88	1.2	0.246	Not significant

The test of significant i.e. t_{19}= 1.2, p > 0.01 hence it is a statically in significant it implied that the effect of drug on LDL in group- C not satisfactory.

DISCUSSION:

- Result of the drug (Nephaphu) of Group A, B and C- 60 patients were registered for the clinical trial. Patients of each group possess their own subjective and objective parameters which were specific to them. Although patients were statistically analysed for their subjective and objective parameters with the trial drug before and after treatment. For this specialized grading system was used.

Effect of drug in group A

1. **Systolic BP-** The observation made with respect to systolic BP showed that before treatment the mean systolic BP was 141mmHg and after taking the trial drug of 45 days the mean systolic BP was 133mmHg. Hence the trial drug shows significant efficacy for controlling systolic Blood pressure with the p value <0.0001 which is highly significant.
2. **Diastolic BP-** The observation made with respect to diastolic BP showed that before treatment the mean diastolic BP was 147mmHg and after taking the trial drug of 45 days the mean systolic BP was 133mmHg with p value<0.0001 which is highly significant, Hence the trial drug shows significant efficacy for controlling diastolic Blood pressure.
3. **Symptoms-** Statistically high significant effect(P<0.001) is seen on symptoms like giddiness, headache, lack of sleep and fatigue.
4. Statistically significant level of cholesterol is found with P<0.001 in the group A.

Effect of drug in group B

1. **Systolic BP-** The observation made with respect to systolic BP showed that before treatment the mean systolic BP was 147mmHg and after taking the trial drug of 45 days the mean systolic BP was 137.5 mmHg. Hence the trial drug shows significant efficacy for controlling systolic Blood pressure.
2. **Diastolic BP-** The observation made with respect to diastolic BP showed that before treatment the mean diastolic BP was 93.5mmHg and after taking the trial drug of 45 days the mean systolic BP was 84mmHg. Hence the trial drug shows significant efficacy for controlling diastolic Blood pressure.
3. **Symptoms-** Statistically high significant effect (P<0.001) is seen on symptoms like giddiness, headache, lack of sleep and fatigue.
4. Statistically significant level of cholesterol is found with P<0.001 in the group B.

Effect of drug in group C

1. **Systolic BP-** The observation made with respect to systolic BP showed that before treatment the mean systolic BP was 142.5mmHg and after taking the trial drug of 45 days the mean systolic BP was 133 mmHg. Hence the trial drug shows significant efficacy for controlling systolic Blood

pressure.

2. **Diastolic BP-** The observation made with respect to diastolic BP showed that before treatment the mean diastolic BP was 90.5mmHg and after taking the trial drug of 45 days the mean systolic BP was 85.3mmHg. Hence the trial drug shows significant efficacy for controlling diastolic Blood pressure.
3. **Symptoms-** Statistically high significant effect($P<0.001$) is seen on symptoms like giddiness, headache, lack of sleep and fatigue.
4. Statistically significant level of cholesterol is found with $P<0.001$ in the group C.The above result indicate that patients have shown improvement in the criteria of Hypertension, the 3 groups showed significant result equally when statistically compared before and after treatment. It can be said that the trial drug Nephaphu showed very good result in hypertensive people in lowering the SBP,DBP and along with the symptoms equally in all the 3 groups.

SUMMARY & CONCLUSION:

- 3 groups of patients were registered with 20 patients in each group for clinical assessment i.e Group A (Newly diagnosed case of Hypertension), Group B (Hypertensive patients with or without disturbance of lipid profile, Group C (Chronic hypertension under modern medication amlodipine.)
- Assesement were done with the help of subjective and objective parameters in a spcially designed proforma.
- Grading of the subjective and objective parameters were done to study the improvement.

In Group A, the observations were made in subjective and objective parameters both. Statistically highly significant ($P<0.001$) effect is seen in The subjective parameters i.e the symptoms like headache, giddiness, lack of sleep, fatigue along with decrease in the SBP &DBP. Amongst the objective parameters the value of cholesterol was found highly significant (<0.001) after completion of the treatment. Similarly In Group B & in Group C also highly significant values was found (<0.001) in the symptoms like headache, giddiness, fatigue etc. And objective parameters mainly cholesterol showed significant result <0.001after treatment.

As the study was time bounded and the sample size was small so a large number of patients by evaluating the causative factors of Hypertension in Ayurveda may give a new direction in the study and efficacy of the drug nephaphu in it.

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