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Research Article

A CLINICAL STUDY TO EVALUATE THE ANTIHYPERTENSIVE EFFECT OF *TRINPANCHMOOL KWATH* IN MANAGEMENT OF ESSENTIAL HYPERTENSION

Prerna[1]*, Vijay Chaudhary[2], B.L.Mehra[3]

*[1]Research Scholar, [2]Professor and H.O.D, [3]Professor and Former H.O.D., P.G. Dept of Kayachitiksa, RGGPG Ayurvedic College, Paprola, Himachal Pradesh, India.

KEYWORDS: Hypertension, *Trinpanchmool*, Antihypertensive Effect.

***Address for correspondence**
Dr. Prerna
Research Scholar,
P.G. Dept of Kayachitiksa,
RGGPG Ayurvedic College,
Paprola, Himachal Pradesh,
India.
Email:
doctorprerna198@gmail.com

ABSTRACT

The present study was conducted to evaluate the antihypertensive effect of an Ayurvedic formulation *Trinpanchmool Kwath* in the management of essential hypertension. The study was conducted in 30 patients selected from OPD and IPD of R.G.G. P.G.A.C. and Hospital, Paprola. Patients were randomly divided into three groups. Group-I patients were managed with *Trinpanchmool Kwath*, Group-II patients were managed with Tab Chlorthalidone and Group-III patients were managed with both *Trinpanchmool Kwath* and Tab. Chlorthalidone. The results obtained were analysed on the basis of various objective and subjective parameters. However change in blood pressure was the main criteria for assessing the effect of the therapy. Statistically highly significant reduction was observed in systolic and diastolic blood pressure after 45 days of therapy. In Group-I systolic blood pressure reduced by 9.374%, in Group-II systolic blood pressure decreased by 15.46% and in Group-III systolic blood pressure decreased by 16.86%. Similarly in Group-I diastolic blood pressure decreased by 8.195%, in Group-II showed 11.250% reduction and in Group-III diastolic blood pressure decreased by 12.17% after completion of therapy. Results revealed that therapy given in Group-III i.e. the combination of *Trinpanchmool Kwath* and Tab. Chlorthalidone showed best results as compared to other groups. Group-II, in which patients were managed with Tab Chlorthalidone showed better results over Group-I where only *Trinpanchmool Kwath* was given to the patients. However statistically highly significant reduction in both systolic and diastolic pressure was observed in all three groups.

INTRODUCTION

The WHO has located India as one of the countries that are going to report most of the lifestyle disorders in the near future. The major lifestyle diseases identified in India include Heart disease, Hypertension, Obesity, Diabetes mellitus, and Cancer. Hypertension is multifactorial disorder. Increased stress level, less physical activity, obesity and overuse of salt are among its common aetiological factors. It is known as a worldwide problem as 15-20% of all adults are affected by this condition[1]. Hypertension doubles the risk of coronary heart disease, cardiac hypertrophy with heart failure, aortic distension and renal failure, neurogenic effect and development of cerebro- and cardiovascular disorders[2]. It is also known as a high risk factor for brain ischemia, stroke, arteriosclerosis, end stage renal disease and myocardial infarction[3]. It is expected to cause more than half of the estimated 17 million deaths per year resulting from cardiovascular disease worldwide. Highly populated developing Asian countries, such as India and China, have a large absolute number of individuals with hypertension. Globally, an estimated 26% of the world's population has hypertension, and the prevalence is expected to increase to 29% by 2025[4].

The conventional antihypertensive drugs have many adverse effects and are not well tolerated

which leads to noncompliance, switching, and discontinuation of treatment. So it is a need of the time to get a safe and cost-effective remedy for hypertension.

AIMS AND OBJECTIVES

Primary Objectives

To clinically evaluate the efficacy of *Trinpanchmool Kwath* in the management of essential hypertension.

Secondary Objectives

To assess the safety of *Trinpanchmool Kwath* in the patients of essential hypertension.

MATERIALS AND METHOD

Selection of Patient

Total 30 study subjects were selected from OPD/IPD of R.G.G.P.G. Ayurvedic College and Hospital, Paprola, Dist. Kangra (H.P.), irrespective of caste, gender, race and religion. A detailed history was obtained, physical examination was conducted and relevant investigations of study subjects were carried out before the enrolment and after the completion of trial period.

Protocol of Research

1. **I.E.C Approval:** The detailed synopsis of the study was submitted to I.E.C. and after getting clearance from committee this study has been undertaken. IEC clearance was obtained vide letter No. Ayu/IEC/2017/1138 Dated 1/10/2018.
2. **Consent:** Written and informed consent of patients was taken before inclusion in the trial.
3. **CTRI registration:** The study has also been registered in clinical trial registry of India vide CTRI No. CTRI/2019/11/022015 dated 15/11/2019.

History Performa

A special case history proforma was prepared. All the sign/symptoms, blood pressure reading were depicted in this proforma along with pulse pressure, before inclusion and after completion of study**.**

Criteria of Diagnosis

Diagnosis was mainly based on readings of sphygmomanometer. With the help of sphygmomanometer, 3 consecutive reading of blood pressure in 3 different positions (sitting, standing and supine) on both arms were taken. Their mean value was calculated for each arm separately and the highest reading was utilized for diagnosing and categorizing the patients according to 7th Joint National Committee on Detection, Education and Treatment of High Blood Pressure. Only newly diagnosed patients of stage– I hypertension were included in trial according to JNC7 guideline. To determine systolic and diastolic blood pressure the Kortokoff sound 1 and 5 were used.

Inclusion criteria

a) Patients willing for trial.
b) Patients in age group between 20–70 years.
c) Patients suffering from stage-I hypertension (i.e. Systolic Blood Pressure 140–159mm of Hg and Diastolic Blood Pressure 90–99mm of Hg according to JNC7).
d) Patients suffering from isolated systolic hypertension (i.e. Systolic Blood Pressure 140-159mm of Hg and Diastolic Blood Pressure <90mm of Hg).

Exclusion criteria

a) Patients not willing for the trial.
b) Patients < 20 years and >70 years of age.
c) Stage II hypertension i.e. Systolic ≥ 160mmHg and Diastolic ≥ 100mmHg.
d) Patients suffering from secondary hypertension.
e) Any other condition which the principal investigator thought may jeopardize the study.
f) Patients who had participated in any clinical study/trial in past 6 months.

Investigations

Hb%, TLC, DLC, ESR, FBS, Blood Urea, Serum Creatinine, SGOT, SGPT, S. Lipid profile (S. Cholesterol, S.Triglycerides, HDL, LDL, VLDL), Urine- Routine and Microscopic examination

Method of Study

Total 30 patients of Hypertension were selected for the present clinical study; they were randomly divided and managed into the following groups:

Trial Group I- Total 10 patients were registered in this group out of them, 9 patients completed the trial. In this group hypertensive patients were managed with *Trinpanchmool Kwath*.

Trial Drug

Interventional products were prepared at Government Charaka Ayurvedic Pharmacy, Paprola vide Licence No.HP-Ay-87.

Table 1: Ingredients of *Trinpanchmool Kwath*

S. No	Name	Latin name	Family	Part used	Proportion
1.	*Kush*	*Desmostachya Bipinnata*	Poaceae	Root	1 part
2.	*Kash*	*Saccharum Spontaneum*	Poaceae	Root	1 part
3.	*Shara*	*Saccharum Munja*	Poaceae	Root	1 part
4.	*Ikshu*	*Saccharum officinarum*	Poaceae	Root	1 part
5.	*Darbh*	*Imperata cylindrical*	Poaceae	Root	1 part

Dosage: *Trinpanchmool Kwath* was given in the dose of 50ml BD.

Trial Group II: Total 10 patients were registered in this group out of them, 9 patients completed the trial. In this group patient were managed with Tab. Chlorthalidone in the dose12.5mg once a day.

Trial Group III: Total 10 patients were registered in this group, all of them completed the trial. In this group patients were managed with both *Trinpanchmool Kwath* 50ml BD and Chlorthalidone 12.5mg OD.

Duration of Trial- 45 days

Follow up and Assessment of the Study Subjects:

A thorough assessment of the study subjects was done before commencement of the therapy (day zero) and at the 15th, 30th and 45th day i.e. at the time of the completion of therapy. The effects of treatment were assessed on the basis of various subjective and objective parameters. However the change in systolic, diastolic and mean blood pressure was the main criteria. Laboratory investigations were carried out before commencement and after completion of the treatment.

A) Objective Criteria

- Systolic and Diastolic Blood Pressure
- Pulse Pressure
- Mean Arterial Pressure

B) Subjective Criteria

Subjective parameters were graded from 0 to 3 according to severity.

Shiroruja

***Shiroruja* (Headache)**	**Score**
No Headache	0
Mild headache but patient was able to do casual work	1
Continuous headache which hampers routine work	2
Patient unable to do routine work	3

***Bhrama* (Giddiness)**

***Bhrama* (Giddiness)**	**Score**
Giddiness	0
Occasional but patient able to do usual work	1
Continuous giddiness which hampers routine work	2
Patient unable to do any work	3

***Hridadrava* (Palpitation)**

Hridadrava	**Score**
No palpitation	0
Occasional palpitation	1
Palpitation hampers routine work	2
Continuous palpitation	3

***Swasa Kricchrita* (Breathlessness)**

Swasa Kricchrita	**Score**
No dyspnoea on exertion	0
Mild dyspnoea and able to do routine work	1
Moderate dyspnoea which hampers routine work	2
Dyspnoea at rest making patient unable to do routine work	3

Statistical Assessment

Data generated during study was collected and analyzed statistically. The improvement in the status of patient was assessed on the grades of various variables compared between pre trial and post trial values in terms of percentage (based on mathematical mean and its difference) and also paired 't' test and Anova test was applied wherever it was felt necessary. The result were interpreted at the level of $p<0.001$as highly significant, $p<0.05$ as significant and $p>0.05$ as insignificant.

OBSEVATIONS AND RESULTS

Out of 30 registered study subjects maximum were married (96.67%) female (56.67%) of age group between 55-70 yrs (46.67%) dwelling in rural area (98.33%) and Hindu (100%) by

religion.46.67% were educated up to metric and majority of them were involved in house work (33%), taking mixed diet 76.67%) and having normal sleep (66.67%). 23.33% of study subjects had no addiction but rest of them were addicted either to smoking or alcohol. Majority of individuals had *Vata-Pittaj Deha Prakriti* (63.33%) and *Rajsik Manas Prakriti* (73.33%). Majority were *Mamsa Sara* (43.33%) with *Madhyam Samhanana* (100%), *Satva (83.33%), Satmaya (60%), Pramana (90%)* and *Madhyama Aahara Shakti* (70%) and *Vyayama Shakti* (50).

Table 2: Effect of Therapy on Objective Criteria

Objective Criteria	Group	Mean Score		Percent Change
		BT	AT	
Systolic Blood Pressure (in mm of Hg)	Group-I	148.60	134.67	9.37%
	Group-II	150.10	126.89	15.46%
	Group-III	153.00	127.20	16.86%
Diastolic Blood Pressure (in mm of Hg)	Group-I	89.80	82.44	8.19%
	Group-II	92.40	82.00	11.25%
	Group-III	92.00	80.80	12.17%
Mean Arterial Pressure (in mm of Hg)	Group-I	109.70	99.73	9.08%
	Group-II	112.01	96.93	13.46%
	Group-III	112.29	96.24	14.28%
Pulse Pressure (in mm of Hg)	Group-I	59.8	52.0	13.04%
	Group-II	58.9	44.8	23.70%
	Group-III	61.0	46.4	23.93%
Pulse Rate (per minute)	Group-I	76.40	74.00	3.14%
	Group-II	73.20	73.11	0.12%
	Group-III	76.80	73.00	4.94%

Objective Criteria	Group	Mean Diff.	SD±	SE±	't' value	'p' value	Intergroup p-value
Systolic Blood Pressure (in mm of Hg)	Group-I	13.11	6.009	2.003	6.545	<0.001	0.002
	Group-II	22.56	9.710	3.237	6.969	<0.001	
	Group-III	25.80	4.050	1.281	20.146	<0.001	
Diastolic Blood Pressure (in mm of Hg)	Group-I	7.33	4.472	1.491	4.919	<0.001	0.187
	Group-II	10.22	5.696	1.899	5.384	<0.001	
	Group-III	11.20	3.425	1.083	10.340	<0.001	
Mean Arterial Pressure (in mm of Hg)	Group-I	9.71	5.192	1.731	5.611	<0.001	0.013
	Group-II	14.78	5.545	1.848	8.002	<0.001	
	Group-III	16.04	2.170	0.686	23.386	<0.001	
Pulse Pressure (in mm of Hg)	Group-I	7.11	5.487	1.829	3.888	0.005	0.071
	Group-II	13.67	11.790	3.930	3.478	0.008	
	Group-III	14.60	6.186	1.956	7.464	<0.001	
Pulse Rate (per minute)	Group-I	2.44	6.839	2.280	1.072	0.315	0.672
	Group-II	0.67	7.180	2.603	0.256	0.804	
	Group-III	3.80	8.025	2.538	1.497	0.169	

Table 3: Effects of therapy on Subjective Criteria

Criteria	Group	Mean Score		Percent Change
		BT	AT	
Headache (*Shiroruja*)	Group-I	1.6	1.1	30.64%
	Group-II	1.4	0.7	44.24%
	Group-III	1.9	0.9	52.63%
Giddiness (*Bhrama*)	Group-I	1.1	0.6	40%
	Group-II	1.2	0.6	53%
	Group-III	1.7	0.7	58%
Palpitation (*Hriddravata*)	Group-I	0.5	0.2	55.6%
	Group-II	0.7	0.2	68.2%
	Group-III	0.7	0.1	85.7%
Breathlessness (*Shwas Krichhrita*)	Group-I	0.4	0.2	44.5%
	Group-II	1.2	0.6	53%
	Group-III	1.0	0.4	60%

Criteria	Group	Mean Diff.	SD±	SE±	't' value	'p' value	Intergroup p-value
Headache (*Shiroruja*)	Group-I	0.667	0.500	0.167	4.000	0.004	0.307
	Group-II	0.778	0.441	0.147	5.292	<0.001	
	Group-III	1.000	0.471	0.149	6.708	<0.001	
Giddiness (*Bhrama*)	Group-I	0.444	0.527	0.176	2.530	0.035	0.068
	Group-II	0.667	0.500	0.167	3.500	0.004	
	Group-III	1.000	0.471	0.149	6.000	<0.001	
Palpitation (*Hriddravata*)	Group-I	0.333	0.500	0.167	2.000	0.081	0.614
	Group-II	0.444	0.527	0.176	2.530	0.035	
	Group-III	0.600	0.699	0.221	2.714	0.024	
Breathlessness (*Shwas Krichhrita*)	Group-I	0.111	0.333	0.111	1.000	0.347	0.065
	Group-II	0.556	0.527	0.176	3.162	0.013	
	Group-III	0.600	0.516	0.163	3.674	0.005	

Table 4: Effect of therapy on Hematological Profile

Variable	Group	Mean Score		Percent Change
		BT	AT	
Haemoglobin	Group-I	12.66	12.68	0.16%
	Group-II	12.57	12.68	0.95%
	Group-III	11.71	11.76	0.43%
TLC	Group-I	6611.11	6900.00	1.03%
	Group-II	6890.00	6900.00	0.15%
	Group-III	6140.00	6223.00	1.33%
ESR	Group-I	20.00	19.56	2.20%
	Group-II	17.00	16.80	1.18%
	Group-III	14.0	13.8	1.43%

Variable	Group	Mean Diff.	SD±	SE±	't' value	'p' value
Haemoglobin	Group-I	0.09	1.203	0.380	0.237	0.818
	Group-II	0.01	0.513	0.171	0.064	0.950
	Group-III	0.05	0.576	0.182	0.275	0.790
TLC	Group-I	244.44	418.66	139.55	1.752	0.118
	Group-II	38.33	245.52	81.838	0.543	0.602
	Group-III	83.00	201.11	63.597	1.305	0.224
ESR	Group-I	1.89	3.480	1.160	1.628	0.142
	Group-II	0.89	3.756	1.252	0.710	0.498
	Group-III	0.33	2.582	0.816	1.225	0.252

Table 5: Effect of therapy on Biochemical Profile

Variable	Group	Mean Score		Percent Change
		BT	AT	
FBS	Group-I	90.80	94.11	3.65%
	Group-II	92.10	90.67	1.55%
	Group-III	94.40	93.70	0.74%
B. Urea	Group-I	24.60	23.89	2.89%
	Group-II	27.70	27.00	2.52%
	Group-III	30.90	30.20	2.26%
S. Creatinine	Group-I	0.91	0.89	2.31%
	Group-II	0.90	0.88	2.44%
	Group-III	0.87	0.84	3.44%
SGOT	Group-I	34.80	33.22	4.53%
	Group-II	30.80	30.11	0.74%
	Group-III	38.10	37.80	0.78%
SGPT	Group-I	21.40	21.00	1.87%
	Group-II	30.00	29.78	0.74%
	Group-III	33.80	32.90	2.66%
S. Cholestrol	Group-I	166.90	161.00	3.54%
	Group-II	169.90	169.20	0.41%
	Group-III	169.90	167.40	1.47%
Triglycerides	Group-I	185.00	180.00	2.70%
	Group-II	191.90	183.78	4.23%
	Group-III	113.80	112.90	0.79%
HDL	Group-I	55.20	53.89	2.35%
	Group-II	59.40	57.11	3.85%
	Group-III	64.20	66.10	2.96%
LDL	Group-I	89.20	84.44	5.33%
	Group-II	89.20	86.11	3.46%
	Group-III	83.40	81.70	2.04%
VLDL	Group-I	43.50	42.22	2.93%
	Group-II	42.00	41.22	1.85%
	Group-III	26.80	25.90	3.36%

Variable	Group	Mean Diff.	SD±	SE±	't' value	'p' value
FBS	Group-I	2.67	10.075	3.358	0.794	0.450
	Group-II	0.56	4.216	1.405	0.395	0.703
	Group-III	5.30	14.667	4.638	1.143	0.283
B. Urea	Group-I	0.56	1.424	0.475	1.170	0.276
	Group-II	0.44	1.590	0.530	0.839	0.426
	Group-III	0.70	6.684	2.114	0.331	0.748
S. Creatinine	Group-I	0.03	0.180	0.060	0.555	0.594
	Group-II	0.02	0.067	0.022	1.000	0.347
	Group-III	0.03	0.149	0.004	0.635	0.541
SGOT	Group-I	0.33	20.803	6.934	0.048	0.963
	Group-II	0.22	1.202	0.401	0.555	0.594
	Group-III	0.33	12.193	3.856	0.856	0.414
SGPT	Group-I	0.22	0.450	0.494	0.450	0.665
	Group-II	0.22	4.919	1.640	0.136	0.896
	Group-III	0.90	1.912	0.605	1.489	0.171
S. Cholesterol	Group-I	0.22	57.286	19.095	0.012	0.991
	Group-II	0.70	8.301	2.625	0.267	0.796
	Group-III	2.50	8.985	2.841	0.880	0.402
Triglycerides	Group-I	5.00	24.367	8.122	0.862	0.414
	Group-II	20.56	98.434	32.811	0.626	0.548
	Group-III	0.90	29.316	9.271	0.097	0.925
HDL	Group-I	0.22	12.686	4.229	0.052	0.959
	Group-II	3.11	5.798	1.933	1.610	0.330
	Group-III	1.90	11.396	3.604	0.527	0.611
LDL	Group-I	3.33	14.309	4.770	0.699	0.504
	Group-II	1.67	11.057	3.686	0.452	0.663
	Group-III	3.70	11.676	4.008	1.422	0.189
VLDL	Group-I	0.28	4.062	1.354	1.477	0.178
	Group-II	0.78	17.937	5.312	0.775	0.461
	Group-III	1.50	8.631	2.729	0.550	0.596

DISCUSSION

In present study maximum patients were females. It may be because the prevalence of hypertension is more in females after the age of 40. This suggests that the oestrogen probably play a part in preventing or delaying hypertension[5].

Maximum patients had sedentary life style. Sedentary life style associated with several cardiometabolic factors, including obesity, low high-density lipoprotein cholesterol, high triglycerides etc. are the main risk factors of blood pressure, which in long run can lead to development of systemic arterial hypertension[6]. In present study patients were found addicted to alcohol and smoking. Factors like alcohol consumption and smoking are documented determinants of hypertension. Addiction of alcohol has been reported in 5 to 30% of all hypertensive and also causes resistance to antihypertensive treatments. Maximum registered patients were

taking mixed diet. In different research it was found that vegetarians had blood pressure that was significantly lower than who took non-vegetarian diet. Although the available evidence is limited, according to a previous meta-analysis of controlled trials, vegetarian dietary patterns significantly reduced systolic and diastolic blood pressure. One of the common features of a vegetarian diet is weight loss, which might, at least partially, explain the effect on BP. Other possible factors such as sodium, potassium, protein, amino acids, vitamin B-12, antioxidants, fiber, and the microbiome are introduced as possible mechanisms[7].

In the present study maximum registered patients had *Madhyama Vyayama Shakti* and *Avara Vayayam Shakti.* Exercise increases blood circulation, reduce platelet stickiness, increases fibrinolysis, lower blood lipids and reduces obesity. Exercise appears to have a positive effect on remodelling of the hypertensive heart and prevention of LVH[8].

The mean score of systolic blood pressure before treatment in Group-I was 148.60mm of Hg which decreased to 134.67mm of Hg after treatment with 9.374% reduction, which was statistically highly significant (p<0.001). In Group-II the initial mean score of systolic blood pressure was 150.10mm of Hg which decreased to 126.89mm of Hg after treatment with 15.46% reduction which was highly significant (p<0.001). Whereas in Group-III initial mean score of systolic blood pressure was 153.00mm of Hg which decreased to 127.200mm of Hg after treatment with 16.86% reduction which was highly significant (p<0.001).

Similarly the initial mean score of diastolic blood pressure in Group-I was 89.8mm of Hg, which decreased to 82.44mm of Hg after treatment with 8.195% reduction which was statistically significant (p=0.001). In Group-II the initial mean score of diastolic blood pressure was 92.4mm of Hg, which decreased to 82.0mm of Hg after treatment with 11.250% reduction which was highly significant (p<0.001). In Group- III the initial mean score of diastolic blood pressure was 92.00mm of Hg, which decreased to 80.80mm of Hg after treatment with 12.17% reduction which was highly significant (p<0.001). The intergroup comparison of effect of therapy on systolic blood pressure observed after the completion of therapy was statistically significant (p= 0.002). The intergroup comparison of effect of therapy on diastolic blood pressure observed after the completion of therapy was statistically insignificant (p =0.187).

In Group- I initial mean score of mean arterial pressure was 109.7mm of Hg which decreased to 99.73mm of Hg after treatment with 9.088% reduction which was statistically highly significant (p<0.001). In Group-II mean score of mean arterial pressure was 112.0mm of Hg which decreased to 96.93mm of Hg after treatment with 13.46% reduction which was statistically highly significant (p<0.001).

In Group III, the initial mean score of mean arterial pressure was 112.29mm of Hg which decreased to 96.24mm of Hg after treatment with 14.28% reduction which was statistically highly significant (p<0.001). The intergroup comparison of effect of therapy on mean arterial blood pressure observed after the completion of therapy was statistically significant (p =0.013).

In Group- I mean score of pulse pressure was 59.8mm of Hg which decreased to 52 mm of Hg after treatment with 13.04% reduction which was statistically significant (p=0.005). In Group II mean score of mean arterial pressure was 58.9mm of Hg which decreased to 44.89mm of Hg after treatment with 23.7% reduction which was statistically significant (p=0.008). In Group III mean score of mean arterial pressure was 61.00mm of Hg which decreased to 46.40mm of Hg after treatment with 23.93% reduction which was statistically highly significant (p=<0.001). The intergroup comparison of effect of therapy on pulse pressure observed after the completion of therapy was statistically insignificant (p= 0.071).

In Group-I, mean score of pulse pressure was 76.40mm of Hg which decreased to 74mm of Hg after treatment with 3.141% reduction which was statistically insignificant (p=0.315). In Group-1I, mean score of pulse pressure was 73.20 mm of Hg which decreased to 73.11mm of Hg after treatment with 0.122% reduction which was statistically insignificant (p=0.804). In Group-III, mean score of mean arterial pressure was 76.80mm of Hg which decreased to 73.00mm of Hg after treatment with 4.947% reduction which was statistically insignificant (p=0.169). On comparing the inter group difference, there was insignificant difference in reduction of pulse rate (p=0.672).

Out of 30 registered patients of Stage 1 Hypertension, 83.33% (25) patients had *Shiroruja*, 83.33% (25) patients had *Bhrama*, 56.67% (17) patients had *Shwasa Kricchta* and 53.33% (16) patients had *Hriddravata*.

In Group-I the initial mean score of *Shiroruja* in Group-I was 1.6, which decreased to 1.11 after treatment with 30.64% reduction which was statistically significant (p=0.004). In Group-II mean score of *Shiroruja* was 1.4 which decreased to 0.778 after treatment with 44.24% reduction which was statistically highly significant (p=<0.001). In Group- III the initial mean score of *Shiroruja* in this group was 1.9 which decreased to 0.90 after treatment with 52.63% reduction which was statistically highly significant (p=<0.001). The intergroup comparison of effect of therapy on *Shiroruja* observed after the completion of therapy was statistically insignificant (p =0.307).

In Group-I the initial mean score of *Bhrama* in group I was 1.1, which decreased to 0.556 after treatment with 40% reduction which was statistically significant (p=0.035). In Group II initial mean score of *Bhrama* was 1.2 which decreased to 0.556 after treatment with 53% reduction which was statistically significant (p=0.004). In Group III the initial mean score of *Bhrama* was 1.7 which decreased to 0.7 after treatment with 58% reduction which was statistically highly significant (p=<0.001). The intergroup comparison of effect of therapy on *Bhrama* observed after the completion of therapy was statistically insignificant (p =0.068).

In Group I the initial mean score of *Hriddrava* was 0.500, which decreased to 0.222 after treatment with 55.6% reduction which was statistically insignificant (p=0.081). In Group-II mean score of *Hriddrava* in was 0.700 which decreased to 0.222 after treatment with 68.2% reduction which was statistically significant (p=0.035). In Group-III mean score of *Hriddrava* was 0.700 which decreased to 0.1000 after treatment with 85.7% reduction which was statistically significant (p=0.024). The intergroup comparison of effect of therapy on *Hriddrava* observed after the completion of therapy was statistically insignificant (p =0.614).

In Group- I the initial mean score of *Shwas Krichhrita* was 0.400, which decreased to 0.222 after treatment with 44.5% reduction which was statistically insignificant (p=0.347). In Group –II, mean score of *Shwas Krichhrita* was 1.200 which decreased to 0.556 after treatment with 53% reduction which was statistically significant (p=0.013). In Group-III, initial mean score of *Shwas Krichhrita* was 1.000 which decreased to 0.400 after treatment with 60% reduction which was statistically significant (p=0.005). The intergroup comparison of effect of therapy on *Shwas Krichhrita* observed after the completion of therapy was statistically insignificant (p =0.065).

Laboratory Profile

Hematological profile of the registered patients under study revealed that Haemoglobin, TLC, DLC and ESR in all three groups were within normal limits both before and after therapy.

Biochemical profile of the registered patients under study revealed that FBS, B. Urea, S. Creatinine, SGOT, SGPT, S.Cholesterol, TG, HDL, LDL, VLDL in all three groups were within normal limits both before and after the therapy.

Hypertension is a *Tridosha Vyadhi* with *Vata* predominance*.* It has *Tridosha Shamaka* property. This drug alleviates vitiated *Vata* by virtue of its *Snigdha Guna, Madhura Rasa* and *Madura Vipaka* and *Pitta* with its *Madhura Rasa*, *Madhura Vipaka* and *Sheeta Veerya* and *Kapha* by its *Kashaya Rasa.* By *Tridosh Shamaka* effect it helps in reducing the blood pressure.

Trinpanchmool is *Mootra Virechniya* drug. These drugs perform their action by decreasing the *Agneyatatva* and increasing the *Jaliyatatva* in the urine. They do *Pitta- Shaman* and *Vata- Anuloman*. In the recent studies all the drugs found to have diuretic property. They was found to be effective in increasing urinary electrolyte concentration (Na^+, K^+ and Cl^-) and increases the urine quantity resulting in reduction of intravascular volume which may in turn lead to reduction in blood pressure.

CONCLUSION

On clinical evaluation, the trial drug *Trinpanchmool Kwath* has proved effective and safe for patients of essential hypertension. Results revealed that therapy given in Group-III i.e., the combination of *Trinpanchmool Kwath* and Tab. Chlorthalidone showed best results as compared to other groups. Group-II, in which patients were managed with Tab Chlorthalidone showed better results over Group-I where only *Trinpanchmool Kwath* was given to the patients. However statistically highly significant reduction in both systolic and diastolic pressure was observed in all three groups. No untoward effect of therapy was observed in both the groups during the entire trial period.

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