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A Comparative clinical evaluation of *Shirodhara* with *Sukhosnajala*, *Tila Tailam* and *Brahmi Tailam* in the management of mild to moderate essential hypertension

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ABSTRACT

In worldwide 25% of population is suffering with Hypertension. As it is an instrumental disease, asymptomatic in nature, it was named as Silent killer. The causative factors of Essential hypertension were Genetic predisposition and environmental factors but these factors are triggered by stress hence it comes under stress related psycho-somatic disorder. In Hypertensive patients, Decrease in 5mm of Hg in SBP and DBP results in decrease in cardiovascular risk, stroke which decreases mortality rate worldwide. The management aspect of modern medical science remains symptomatic with troublesome side effects. The Joint National Committee (JNC 8) guideline advise higher blood pressure goals, less use of several types of antihypertensive medications and suggests lifestyle modification and relaxation are the best initial therapy. In Ayurveda, *Shirodhara* is one of the *panchakarma* therapy meant for relaxation and stress reducing procedure mentioned in *Dharakalpaas* a preventive and curative treatment for many stress related disorders. So, Present study is planned as "A Comparative clinical evaluation of *Shirodhara* with *Sukhosnajala*, *Tila tailam* and *Brahmitailam* in the management of mild to moderate essential hypertension" was selected. This paper is going to describe about conclusion drawn from the study i.e. effect of three types of dhara on Objective parameters SBP, DBP, PP, and MAP.

Key words: Essential Hypertension, *Shirodhara*, SBP, DBP, PP, MAP.

INTRODUCTION

India is a nation of hypertension declared by ICMR and AIIMS. In India 33% of urban population and 25% of rural population suffer from hypertension^[1] and about ~50 million of US population and worldwide 25% of population were suffering with Hypertension.

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High Blood pressure is a major cardiovascular risk factor^[2-4] and contributes significantly to cardiovascular mortality.^{[5],[6]} Prospective Studies Collaboration has reported that reducing BP can substantially decrease cardiovascular risk and stroke as well as all cause mortality. Reduction of 5mm of Hg in SBP and DBP results in Average Percent Reduction of Stroke incidence by 35-40%,^[7] Myocardial infarction 20-25%, and Heart failure 50%.^[8] Among all hypertension 90 - 95 % comes under Essential Hypertension or primary Hypertension, 10 - 15% comes under secondary hypertension. Secondary hypertension is curable in initial stages. Essential hypertension is a silent killer due to its asymptomatic nature and it is manageable and treatable but not curable.

In stage 3 it directly leads to end organ damage complications without signs and symptoms. Before stage 3 most of the cases relapse in stage 1 to stage 2

i.e., mild to moderate essential hypertension.^[9] In US population out of 100 people, Only 50 people are using Antihypertensive drugs out of which 25 people are maintaining their BP at target goal (140/90) and 25 people are failed to maintain BP levels at set point. The management aspect of modern medical science remains symptomatic with troublesome side effects. So, compared with previous hypertension treatment guidelines, the Joint National Committee (JNC 8) guidelines advise higher blood pressure goals, less use of several types of antihypertensive medications^[10] and suggests lifestyle modification and relaxation are the best initial therapy of choice for prevention of complications there by controlling disease and mortality.^[3] There is a need of exploring safe and effective remedies from Ayurveda. *Shirodhara* is one of the *panchakarma* therapy practised in India over 1400 years for relaxing the mind and widely used in various stress related disorders. Present study is planned as “A Comparative clinical evaluation of *Shirodhara* with *Sukhosnajala*, *Tilatailam*^[11] and *Brahmi Tailam* in the management of mild to moderate essential hypertension” was selected. The purpose of this clinical study is to assess the effect of *Shirodhara* in primary hypertension. If that is effective, the *Dravya* used for *Shirodhara* has any impact on the efficacy. To evaluate this, three groups are formed with three *Dravyas* i.e. *Sukhosnajala*, *Tila Tailam* and *Brahmi Tailam* to do *Shirodhara*. Comparative assessment is done whether the *Dhara* technique is important or the *Dravyas* used to do *Dhara* also has effect on results.

CLINICAL PLAN

Phase - 1

Selection of 60 cases of mild to moderate essential hypertensive patients after proper examining of all criteria are randomly allocated into three groups.

Group A : *Jaladhara*

Group B : *Tila Taila Dhara*

Group C : *Brahmi Taila Dhara*

Phase - 2

All the registered patients who are on Anti-hypertensive drugs will be put on placebo for 4 weeks

to wash out the hypertensive drug effects from the body. Monitoring blood pressure before and after *Shirodhara* average of three readings in supine, sitting and standing position, minimum 10 mins gap is maintained for three postures and 5 mins interval is maintained for each reading was noted during 14 days of treatment.

Phase - 3

Functional evaluation of the condition of hypertensive patients by parameters.

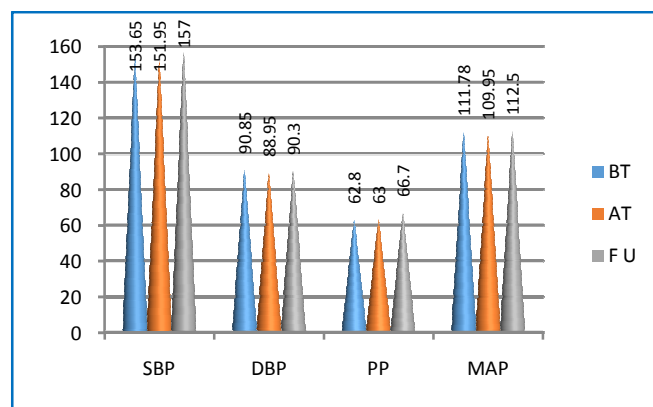
Objective Parameters

1. Systolic blood pressure
2. Diastolic blood pressure
3. Mean arterial pressure
4. Pulse pressure

RESULTS

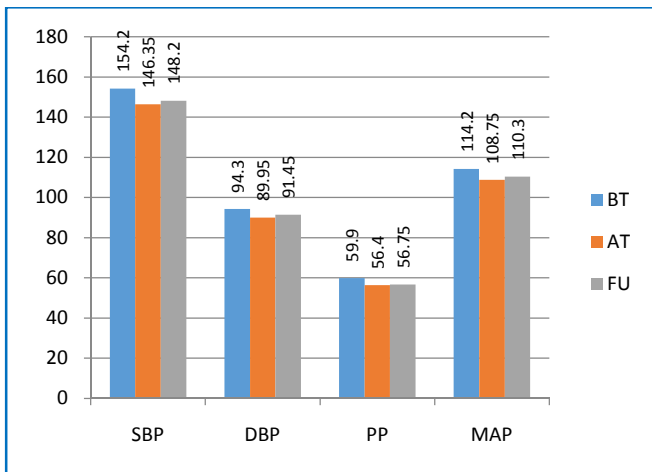
Effect of Group - A (*Jaladhara*) on objective parameters

In *Jaladhara* group, for 20 numbers of patients the total mean of SBP, DBP, PP and MAP before treatment was 153.65, 90.85, 62.80 and 111.78 respectively. After *jalahdara* the total mean of SBP, DBP, PP and MAP was reduced to 151.95, 88.95, 63.00 and 109.95 respectively. But statistically it was not significant as there is no great difference between two total means of all parameters. After 15 days of follow up the total mean of SBP, DBP, PP and MAP was increased to 157.00, 90.30, 66.70 and 112.53 respectively noticed than the before treatment and is negatively significant. So it was concluded that *jalahdara* has some effect on SBP, DBP, PP and MAP after treatment but the effect doesn't lasts longer.



Effect of Group - B (*Tila Taila Dhara*) on objective parameters

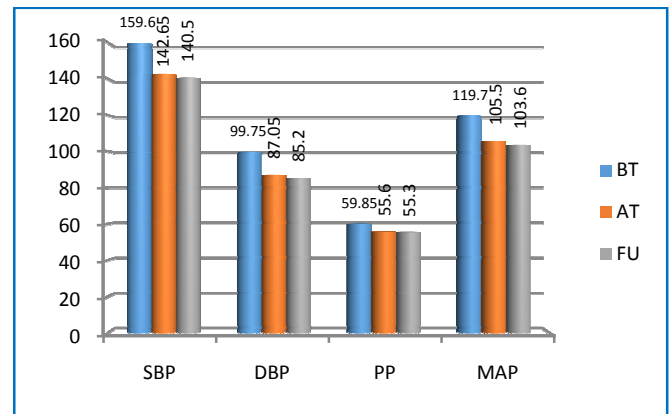
In *Tila Taila Dhara* group, for 20 numbers of patients the total mean of SBP, DBP, PP and MAP before treatment was 154.20, 94.30, 59.90 and 114.27 respectively. After *Tila Taila Dhara* the total mean of SBP, DBP, PP and MAP was reduced to 146.35, 89.95, 56.40 and 108.75 respectively and statistically highly significant at 0.01. After 15 days of follow up the total mean of SBP, DBP, PP and MAP was 148.20, 91.45, 56.75, 110.37 noted and statistically highly significant at 0.01 when compared to before treatment. So it was concluded that *Tila Taila Dhara* decreases SBP and the effect was maintained after follow-up.



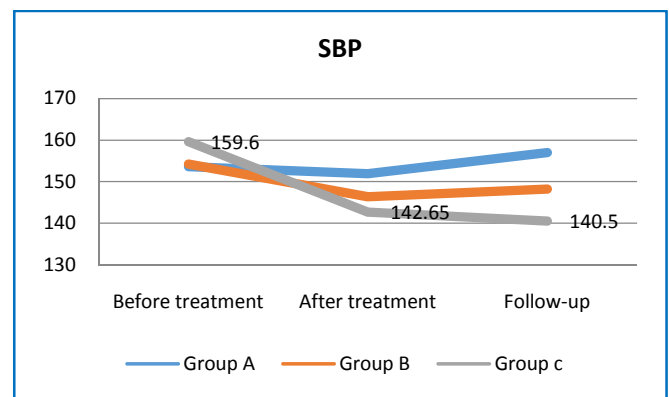
Effect of Group - C (*Brahmi Taila Dhara*) on objective parameters

In *Brahmi Taila Dhara* group, for 20 numbers of patients the total mean of SBP, DBP, PP and MAP before treatment was 159.60, 99.75, 59.85, 119.70 and after *Brahmi Taila Dhara* the total mean of SBP, DBP, PP and MAP was reduced to 142.65, 87.05, 55.60, 105.58 and statistically highly significant at 0.01. After 15 days of follow up the total mean of SBP, DBP, PP and MAP was 140.50, 85.20, 55.30, 103.63 noted and statistically highly significant at 0.01 when compared to before treatment.

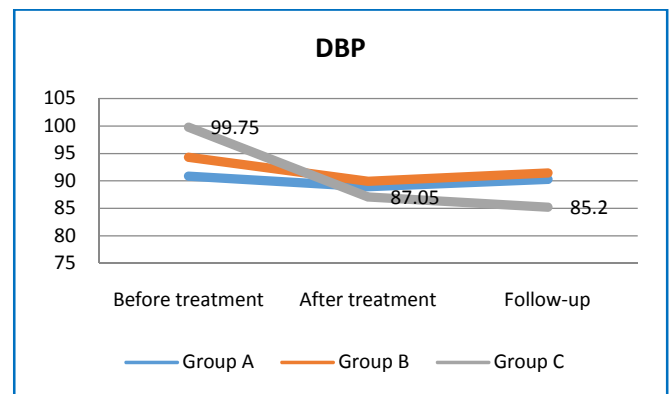
So it was concluded that *Brahmi Taila Dhara* has markedly prolonged effect on SBP, DBP, PP and MAP when compared to Group-B.



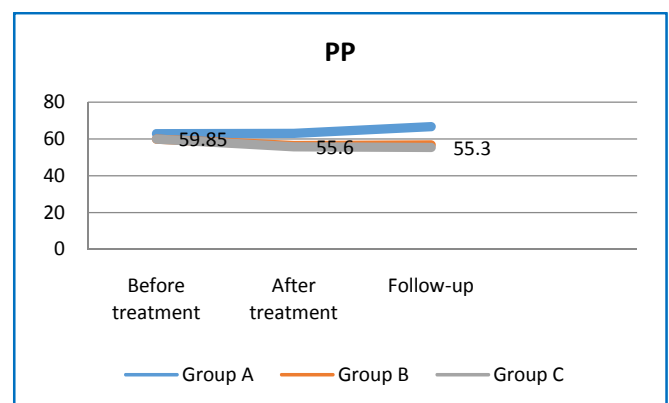
Comparison between three groups on SBP



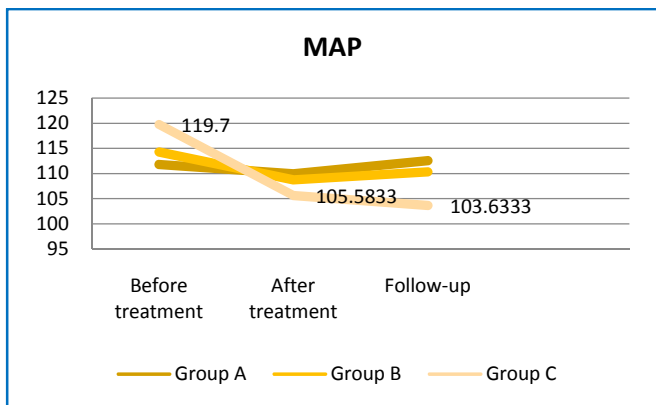
Comparison between three groups on DBP



Comparison between three groups on PP



Comparison between three groups on MAP



Tables showing results within the groups and between the groups;

Table 1: Effects of Jaladhara (Group-A) on objective parameters

Objective Parameters	Comparison B/W	Mean	N	SD	t	p	Remarks	
SBP	SBP BT	153.65	20	14.18	1.987	0.062	NS	
	SBP AT	151.95	20	15.50				
	SBP Follow Up	157.00	20	15.33	5.715	0.000		Negatively significant
DBP	DBP BT	90.85	20	9.34	2.793	0.012	Significant at 0.05	
	DBP AT	88.95	20	9.87				
	DBP BT	90.85	20	9.34	1.037	0.313		NS
	DBP Follow Up	90.30	20	9.70				
PP	PP BT	62.80	20	12.41	0.248	0.807	NS	

	PP AT	63.00	20	12.78			
	PP BT	62.80	20	12.41	5.151	0.000	Negatively significant
	PP Follow Up	66.70	20	13.30			
MAP	MAP BT	111.7833	20	9.5362	2.871	0.010	Negatively significant
	MAP AT	109.9500	20	10.4284			
	MAP BT	111.7833	20	9.5362	1.794	0.089	NS
	MAP Follow Up	112.5333	20	10.0858			

Table 2: Effects of Tila Taila Dhara (Group-B) on objective parameters

Objective parameters	Comparison B/W	Mean	N	SD	t	p	Remarks	
SBP	SBP BT	154.20	20	13.92	17.050	0.000	Significant at 0.01	
	SBP AT	146.35	20	14.11				
	SBP Follow Up	154.20	20	13.92	9.956	0.000		Significant at 0.01
DBP	DBP BT	94.30	20	8.34	12.704	0.000	Significant at 0.01	
	DBP AT	89.95	20	7.70				
	DBP BT	94.30	20	8.34	5.904	0.000		Significant
	DBP Follow Up	94.30	20	8.34				

	DBP Follow Up	91.45	20	8.25			at 0.01
PP	PP BT	59.90	20	10.95	7.315	0.000	Significant at 0.01
	PP AT	56.40	20	10.89			
	PP BT	59.90	20	10.95	4.675	0.000	Significant at 0.01
PP Follow Up	56.75	20	10.41				
MAP	MAP BT	114.2667	20	9.1840	17.628	0.000	Significant at 0.01
	MAP AT	108.7500	20	8.9213			
	MAP BT	114.2667	20	9.1840	9.310	0.000	Significant at 0.01
	MAP Follow Up	110.3667	20	9.1088			

Table 3: Effect of *Brahmi Taila Dhara* (Group-C) on objective parameters

Objective parameters	Comparison B/W	Mean	N	SD	t	p	Remarks
SBP	SBP BT	159.60	20	12.61	39.792	0.000	Significant at 0.01
	SBP AT	142.65	20	12.94			
	SBP BT	159.60	20	12.61	40.673	0.000	Significant at 0.01
	SBP Follow Up	140.50	20	12.99			
DBP	DBP BT	99.75	20	5.48	24.489	0.000	Significant

	DBP AT	87.05	20	4.73			at 0.01
PP	DBP BT	99.75	20	5.48	25.790	0.000	Significant at 0.01
	DBP Follow Up	85.20	20	4.66			
	PP BT	59.85	20	8.99	5.307	0.000	Significant at 0.01
PP AT	55.60	20	10.14				
MAP	PP BT	59.85	20	8.99	5.862	0.000	Significant at 0.01
	PP Follow Up	55.30	20	10.19			
	MAP BT	119.7000	20	7.4173	45.271	0.000	Significant at 0.01
	MAP AT	105.5833	20	6.9188			
MAP	MAP BT	119.7000	20	7.4173	41.236	0.000	Significant at 0.01
	MAP Follow Up	103.6333	20	6.9036			

Table 4: Comparison between groups and within groups

Objective parameters	Comparison	Sum of Squares	df	Mean Square	f	p	Remarks
SBP AT	Between Groups	876.933	2	438.467	2.168	0.124	NS
	Within Groups	11530.050	57	202.282			
	Total	12406.983	59				

SBP Follow Up	Between Groups	2726.533	2	1363.267	6.949	0.002	Significant at 0.01
	Within Groups	11182.200	57	196.179			
	Total	13908.733	59				
DBP AT	Between Groups	86.800	2	43.400	0.727	0.488	NS
	Within Groups	3402.850	57	59.699			
	Total	3489.650	59				
DBP Follow Up	Between Groups	442.633	2	221.317	3.610	0.033	Significant at 0.05
	Within Groups	3494.350	57	61.304			
	Total	3936.983	59				
PP AT	Between Groups	659.733	2	329.867	2.573	0.085	NS
	Within Groups	7307.600	57	128.204			
	Total	7967.333	59				
PP Follow Up	Between Groups	1540.433	2	770.217	5.941	0.005	Significant at 0.01
	Within Groups	7390.150	57	129.652			
	Total	8930.583	59				
MAP AT	Between Groups	203.570	2	101.785	1.293	0.282	NS

	Within Groups	4488.006	57	78.737			
	Total	4691.576	59				
MAP Follow Up	Between Groups	861.615	2	430.807	5.562	0.006	Significant at 0.01
	Within Groups	4414.711	57	77.451			
	Total	5276.326	59				

DISCUSSION

On the basis of this study, it can be concluded that, *Shirodhara* procedure/therapy is recommended not only to relieve stress but also used for prevention of the disease progression by pacifying the signs. In Group A - *Jala Dhara*, After the course of treatment of 14 days, SBP reduced up to 3 mm of Hg, DBP reduced up to 8 -10 mm of Hg, MAP is also came to normal and statistically highly significant at 0.01. No effect was noticed for PP. For follow-up after 15 days, the SBP and PP levels increased than the readings noted before the treatment. DBP and MAP also increased as noted earlier in before treatment. Thus concluded that *jalahdara* effectively reduces peripheral resistance as it decrease diastolic blood pressure up to 10 mm of Hg.

When compared to Group - B *Tila Taila Dhara* no greater mean difference was noted between two groups. Hence it is proved that irrespective of drug used in *Dhara*, the *Shirodhara* procedure itself has clinical efficacy in reducing symptoms. As observed from the results, *Jalahdara* only effective immediately after treatment and it has no long lasting effect on objective parameters while observing the follow-up readings.

In Group B - *Tila Taila Dhara*, After the course of treatment 14 days, SBP reduced up to 8 mm of Hg, DBP reduced up to 8 - 12 mm of Hg, MAP and PP was also came to normal and statistically highly significant at 0.01. For follow-up after 15 days, the SBP, DBP,

MAP and PP levels mildly increased than the readings noted after the treatment but not increased as noted earlier in before treatment. And statistically highly significant at 0.01. Thus concluded that *Tila Taila Dhara* is better than the *Jala Dhara* for long effect on Hypertension. But mild increase of 2 - 4 mm of Hg was noted in both SBP and DBP in Follow-up.

In Group C - *Brahmi Taila Dhara*, After the course of treatment 14 days, SBP reduced up to 15-18 mm of Hg, DBP reduced up to 12-15 mm of Hg, MAP and PP was also came to normal and statistically highly significant at 0.01. For follow-up after 15 days, the SBP, DBP, MAP and PP levels mildly increased than the readings noted after the treatment but not increased as noted earlier in before treatment. And statistically highly significant at 0.01.

During the follow up study, it was found that there was rise in systolic and diastolic pressure suggesting the palliative nature of the treatment. But this rise in blood pressure was early in *Jaladhara* and *Tila Taila Dhara* treated separate groups as compared to the *Brahmi Taila Dhara*. It suggests that effect of *Brahmi Taila Dhara* remains for longer period. Hence comparatively, *Brahmi Taila Dhara* is better than the *Tila Taila Dhara* and *Jaladhara*.

Jaladhara helped in reducing both systolic and diastolic pressure, while *Tila Taila Dhara* reduced both systolic and diastolic pressure in a more pronounced way, where as *Brahmi Taila Dhara* showed speedy improvement than the individual groups. Furthermore, it was also found during treatment that some of the patients improved to such an extent that they had either stopped the modern antihypertensive drug completely or minimized its dose, suggesting that the *Shirodhara* also potentiate the therapeutic efficacy of the modern drug, thus being helpful in avoiding the side effect of modern drug too. On the basis of this study, a better line of management can be offered to the patients, if stress-relieving procedure like *Shirodhara* is given with mental health promoting drugs.

CONCLUSION

Blood pressure depends on several factors mainly on cardiac output and total peripheral resistance. Cardiac output depends on blood volume. Persistent increase in blood volume may cause persistent blood pressure. Blood volume is maintained by stressed volume in the arterial side and unstressed volume in the venous side. Along with genetic pre-disposition some environmental factors especially like chronic psychosocial stress may cause arterial and peripheral vessels constriction causing increased stress volume and unstressed volume respectively. In Ayurveda, *Shirodhara* is a peculiar *Panchakarma* procedure used to relieve the mental stress by relaxing the mind and dilatation of peripheral vessels there by helps in maintaining the blood pressure. In this study all the three groups irrespective of drug *Shirodhara* procedure itself played major role in bringing the objective parameters to normal but the *Shirodhara* procedure with *Dravya* like *Brahmi* showed wonderful results in maintaining the blood pressure.

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