Review Article

Management of Hypertension Through Shodhana & Shamana Chikitsa: A Systematic Review

ABSTRACT:

Hypertension or high blood pressure is a complex disease which may affect other organs resulting in renal dysfunction, neuropathy, cerebral disorders and many other complications. These are further complicated as a result of side effects of established antihypertensive medicines used for it's treatment. A significant rise in cases of hypertension have been noted in the era of modernization. Some alternative or adjuvant modalities is the need of time for the prevention and management of hypertension. As per two basic modules of *Ayurveda, i.e. Hetu, Linga*, it is easy to correlate the Hypertension with multiple terminologies such *as Shonitdushti, Raktavruuta Prana* or *Vyanavrutta Prana,* etc. Using these principles of *Ayurveda*, treatment of hypertension is possible safely at a primary stage. Also it can be used as an adjuvant in the management of advanced stage disease. This meta-analysis reflects on *Ayurvedic* interventions like *Shodhana* or *Shamana Chikitsa* used in the management of hypertension. This analysis included 14 clinical studies conducted on 995 participants at different places. *Shodhana & Shamana Chikitsa* were found to play primary or adjuvant role in the effective management of hypertension. This study dictates the need of scientific multi-centric research on hypertension.

Keywords: Hypertension*, Ayurveda, Shodhan, Shamana, Chikitsa*, Meta-analysis.

INTRODUCTION

Hypertension is a non-communicable disorder that is chronic in nature. According to WHO, the patient having systolic & Diastolic blood pressure more than 140mmHg &90 mmHg, respectively, are diagnosed hypertensive [1]. Mainly, it is a lifestyle disorder that is found in a wide range in the current era of modernization due to faulty lifestyle and stressful psychological conditions. Overall prevalence of Essential Hypertension in India is 29.8%[2].

Due to uncontrolled HTN can create emergencies like CHD (Coronary Heart Disease), Coarctation of Aorta, C.R.F. (Chronic Renal Failure), Myocardial Infarction, etc[3]. These complications may lead to further mortality and catastrophic health expenditure[4]. Therefore, there is a need to control it. In modern medicine, there is a list of various contemporary drugs, e.g., Diuretics (Thiazides, loop diuretics, K-sparing diuretics, fixed-dose combination) to control the blood pressure[5]. However, these causes multiple side-effects such as orthostatic hypotension, sexual dysfunction, hemolytic anemia etc Due to these side-effects, their use should be done cautiously in clinical conditions such as hyperkalemia, renal failure, cough or angioedema[6]. Moreover, these medications have to be

recommended for life time[7]. In a nutshell, these medications do not alter the pathogenesis of the disease & don't lower the risk of complications[8].

Considering the above need-based scenario, it becomes imperative to search or review safe & effective interventions for the management of Hypertension in alternative science, i.e., *Ayurveda.* An *Ayurveda* is a holistic science who recommends preventative approach vigorously rather than the curative approach. It is based upon three basic modules, i.e., *Hetu* (etiological factors), *Linga* (Symptoms) & *Aoushadha,* i.e., therapeutic interventions [9]. Our ancient Acharyas highly appreciate the use of this triad in all diseases, especially for the illness which are not described in the sculptures. In this context, Hypertension in contemporary science is such as a clinical entity which comes under *Anukta Vyadhi.* There is narration regarding symptoms and complications caused by Hypertension in *Ayurvedic* treatise under terminologies such as *Shonitdushti, Raktavruttavata, Or Pranavrutta Vyanavayu* etc. All symptoms of these *Ayurvedic* clinical conditions mimic with modern clinical features of H.T.N. such as headache (*Shiroruk)*, dizziness (*Bhrama*), Irritability (*Krodhaprachurata*), visual disturbances (*Akshiraga*), seizures (*Kampa)*, etc. [10directly or indirectly]. Therefore, it becomes wise to treat this disease by taking into consideration vitiated *Dosha, Dushaya, Strotas*, pathology & its etiological factors, i.e., *Ahara*&*Vihara* vitiating *Tridosha* &*Rakta*. Many research shows that *Shodhana* and *Shamana* are more effective as compared to only *Shamana*. With the help of these *Ayurvedic* measures, we can check over the pathogenesis of Hypertension, prevent various complications of Hypertension in the future[11] as well as avoid the side-effects of current antihypertensive agents by minimizing their doses. Adoption of these measures or adoption of a healthy lifestyle recommended by *Ayurveda* in the primary stage of this disease can also prevent its occurrence & prevalence rate.

Aim & Objectives

Aim

This systemic review study is primarily planned to review previous conducted clinical research based on the type of intervention i.e. various pharmacological & non-pharmacological (*Shodhana &Shamana,* or combination of both) used for management of Hypertension& to make its specific treatment protocol.

Objectives:

To assess the efficacy and safety of *Shodhana &Shamana Chikitsa* or their combinations for management of Hypertension.

Materials & Methods:

All related information is compiled from previous research studies, i.e., Randomized& non-randomized control trials having interventions with *Shodhana &Shamana Chikitsa* for the management of Hypertension & published in various peer-reviewed Journals, & available on multiple databases such as Pubmed, Google scholars, Shodhaganga, and the Cochrane Library, etc. from the year 2000 to April 2020 irrespective of their Study center. References of key articles were hand-searched using the keywords such as "*Shodhana Chikitsa*," "*Shamana Chikitsa*" "*Vamana," Virechana" Vasti," Nasya," Takradhara," Shirodhara*" "Hypertension," "herbal drugs," "Herbo-mineral combination " and experts in the field were

contacted for additional studies. Only English language publications were eligible for inclusion. Both the screening of" title and abstract" and "full text" of the retrieved articles were conducted independently by two reviewers, and a third reviewer resolved any disagreement. A narrative synthesis of the characteristics of study participants and types of intervention with specific outcomes are mentioned.

Study selection

- **Inclusion criteria**

Meta-analysis was focused entirely on only *Ayurvedic* controlled clinical trials(randomized and non-randomized controlled trials conducted in Patients with Hypertension within duration year 2000 to April 2020.

- **Exclusion criteria**

Ayurvedic review articles on Hypertension, *Ayurvedic* clinical studies conducted on complications of Hypertension, related Animal Studies, Case study or case series & modern studies were excluded from the study.

- **Assessment Parameters**

These studies were assessed based on the Inclusion &Exclusion criteria, type of methodology, assessment parameters , type of intervention used (*Shodhana, Shamana Chikitsa* or their combination) and its outcomes measures reported.

Observations & results

A total of 104 articles were retrieved after searching the selected database i.e. Pubmed, Google scholars, Medknow, Web of Science. & Shodhaganga using a comprehensive search strategy. On extensive review of literature from the above sources, due to duplication, 14 articles were removed. Among the rest of 90 items sorted based on screening as per title & abstract, 40 articles were omitted as not related to the aim of the study & objectives. Full text 40 articles were identified, but among them, 26 were withdrawn as those were not related to methodology. These 26 articles were excluded due to the following reasons: 03 articles were a literature review,03 were case reports, and 04 were Observational studies& the rest of 16 didn't not follow methodology, inclusion, and exclusion criteria.

A systematic review is synthesized based on information from a total 14 interventional studies by critically analyzing them to verify the necessity and assess the role of *Shodhana &Shamana Chkitsa*. Among these14, there were observed 9 R.C.T.s (708 participants) and five non-randomized controlled clinical trials (287 participants)in which total 995 hypertensive patients underwent for *Ayurvedic* interventions. Among these 14trials,4 Studies were carried out at I.P.G.T. & R.A. Hospital, G.A.U., Jamnagar, and ten studies were carried out at various study centers throughout India. The detailed description of the selection process of the included articles has been provided in Fig. 1 using P.R.I.S.M.A. flow diagram. Details of clinical studies conducted over hypertensive patients are as follows:

1.**Murthy A.R et al. 2000**[12]

In this clinical, 75 hypertensive patients were recruited by dividing them into three groups (n=25 in each group). Group A & Group B were prescribed with *Ghana Satva Vati* (soft gelatin capsule) of *Gokshura Panchanga* & fruits respectively (capsule orally at the dose of 3

gm/day T.D.S. Group C(control group) was treated with soft gelatin capsule of lactose I.P. (orally at the dose of 3 gm/day in three divided doses). Standard treatment of Hypertension was common for all three groups. Total study duration was 1month with follow up after each week.

After completion of the study, B.P., and symptoms such as headache, giddiness, insomnia, palpitation, swelling were assessed, which has been found significantly reduced in all three groups. The mean S.B.P. was decreased by 170.67 to 152.33, 171.69 to 155.18 & 153.96 to 151.26 in group A.B.& C respectively.

There was a higher significant reduction in systolic blood pressure& DBP was obtained in Group A (18.66) than Group B(17.41). Moreover, DBP was reduced by 104.17 TO 95.78, 104.97 to 97.21 & 101.15 to 99.78 in group A.B.& C respectively after one month of therapy. While the comparison between groups, it was found that significant reduction in systolic& diastolic blood pressures with serum cholesterol level in both Group A & B were more than the control group. However, The more marked effect was found in Group A. After the completion of this study, it was found that *Gokshura* has a significant antihypertensive effect over both systolic and diastolic without any side effects.

2. Bhogayata K. et al. .2009[13]

In this clinical study conducted for the of 21days with follow up for 21 days, newly detected 30 patients of essential Hypertension were enrolled. The study was population was divided into two groups, i.e., n=15 each group. The trial group (Group 1)was prescribed with the decoction of the bark of *Saptaparna,* i.e., 15gm twice a day for 21 days &control group, i.e. (Group 2) was on their regular *SarpagandhaVati* 250mg twice daily for 21days. Regular monitoring of B.P. in sitting position and the supine position was done along with assessments of 18 clinical features of H.T.N.

At the end of the study, it was found that *Sarpagandha Ghana Vati* found more effective in systolic blood pressure in both position with improvement, i.e., % of relief in Psychological symptoms such as *Shirshoola* 8.57%, *Anidra* 80.64%, *Daurbalya* 76.47%, *Bhrama* 85.71%, *Tama* 86.36%, *Urahshul* 83.33%, *Shwasakashtata* 100.0%, *Pindikidveshta* 76.92%, *Vibhandha* 76.19%, *Swedapravrutti*76.19%, *Shirogaurav* 90.0%, *Urogaurav* 61.53% *Arati* 78.57%, *Alasya* 78.94%, *Hridravata* 75.0%, *Akshiraga* 63.15%, *Krodha Prachurata* 82.75%, *Padashotha* 71.42%, etc.

% of Relief in symptoms due to intervention in control group showed headache 82.75%, *Anidra*86.48%,*Daurbalya* 62.90%, *Bhrama*67.50%,*Tama*86.36%,*Klama* 84.21% *Swasakashtata* 65.62%,*Pindikidveshta* 72.0%,*Vibhandha*54.54%, *Swedapravrutti*76.19%,*Shirogaurav*83.87%,*Urogaurav*90%*Arati*84.21%,*Alasya*78.94%,*Hridravata* 69.56%,*Akshiraga* 63.63%,*KrodhaPrachurata* 84.61%,*Urahshul* 55.55%,*Padashotha* 60% etc.

Though there were highly significant reduction observed in systolic and diastolic blood pressure in both sitting and supine position for both groups, however, better improvement has been noted in systolic blood pressure& diastolic blood pressure in both the position in *Sarpagandha* group & in *Saptaparna* Group respectively. *Sarpagadha Ghana Vati* is found more effective in Systolic Blood Pressure (S.B.P.) in both positions(Supine & sitting) with the involvement of psychological symptoms like *Anidra, Arati, Krodhaprachurata* etc.

3. Ananthasayan G.H. 2010[14]

This clinical study was conducted over newly diagnosed 30 patients of Hypertension for 45 days. All patients underwent for *Virechana* with *Trivritlehya* (10-15 grams as per *Kostha)*. Prior *Virechana,* all patients were prescribed for *Dipana Pachana* with *Panchakola Churna*(3 gms TDS till attainment of *Samyaka Dipana Pachana Lakshana*), followed by *Samyak Snehapana* with *Moorchita Tila Taila* 30 ml /day till attainment of *Samyaka Snigdha Lakshana* followed by *Sarvanga Abhyanga* and *Ushna Jala Snana*. After following *Samsarjana Karma* properly, all patients were prescribed for *Shaman Chikitsa* with a cap. *Tagara* 1 capsule twice daily with specific lifestyle modifications.

The total duration of treatment was 45 days. Assessment was done based on blood pressure and Clinical symptoms. At the end of the study, , Mean systolic and diastolic B.P. reduced from 159.46 TO 130 mm of Hg & Mean diastolic B.P. was decreased from 90.60 to 82.6667 mm/hg. Researchers quoted that *Snehapoorvaka Virechana,* followed by shaman *Aushadha,* i.e., *Tagara,* showed highly significant results in freshly detected H.T.N. cases. Along with medicine, dietic restriction of salt and absence from risk factors also play an essential role.

4. Mishra J.et al. (2012) [15]

It was the randomized, single-blind, controlled clinical study conducted over 20 hypertensive patients for eight weeks. The study population was divided into two groups. Group A(n= 10)was prescribed with *Sarpagandhadi Ghana Vati* 2 gm per day in divided doses along with restricted diet pattern for eight weeks and control group, i.e., Group B was advised to take *Shankhapushpyadi Ghana Vati* 2 gm a day in divided doses along with restricted diet pattern for eight weeks.

After intervention, in Group A, Systolic & diastolic Blood pressure was reduced significantly by 8.91% & 8.44% respectively. Moreover, there was observed significant improvement in symptoms e.g. *Shiroruka* 84.61%, *Bhrama* 75%, *Hriddravata* 66.67%, *Ayasjanya Swaskruchhata* 52.94%, *Alpanidra* 69.56%, *Urahshopha* 80.0%, *Daurbalya* 56.67%, *Klama* 51.85%, *Arati* 57.14%, *Santana* 54.54%, *Tamodarshana* 33.33%, *Buddhisammoha* 78.26%, *Krodhaprchurya* 78.57%, *Malavardhana* 74.07%, *Smrutinasha* 84%, *Aruchi* 91.66%, *Akshirga* 54.54% .

In Group B, Systolic & diastolic Blood pressure was reduced significantly by 12 % & 11.02%, respectively. This decrease was more as compared to group A. This study concluded that *Shankhapushpyadi Ghana Vati* had found better efficacy as compared to group b with *Sarpagandhadi Vati*.

5. Shukla G.et al.2013[16]

In this comparative clinical study, the total 40 patients of Hypertension were recruited by dividing them into two groups, i.e., A and B. Among them, for Group A(n=20), *Virechana Karma* with the combination of 100g of *Trivrut Yava Kuta*, 50g of *Aragvadha Phalamajja*, 70 ml of *Eranda Taila* with 100ml of *Draksha Hima* was administered at 10 a.m. Before that, *Samyak Deepan* and *Pachana* was induced with *Trikatu Churna* 3g twice a day for consecutive 2-3days, *Abhyantar Snehapana* with *Shuddha Goghrita* in incremental pattern (30–50 ml/day) was given according to *Koshtha* and *Agni*, for 3-7 day. *Bahya Snehana* with *Bala Taila* and *Mridu Bashpa Sweda* was done twice for three days .

Whereas Group B (n= 20) was administered with *Kalabasti* regime including 480 ml *Niruha Basti*(60g *Makshika* +5g *Saindhav*+90ml *Tila Taila*+25g *Shatapushpa Kalka* +300ml *Dashmoola Kwath300* ml)&*Anuvasan Basti* with *DashmulaTaila*(60 ml) .

Arjunadi Ghana Vati(2 tablets (500 mg each) was prescribed twice in a day with lukewarm water after meal after seven days in both the groups for 30 days.

It was observed that group A, i.e., *Virechana Karma*, was found significantly effective to decrease in S.B.P. & DBP by 7.09% & 5.07 respectively after *Sansarjana Krama*. In comparison, SBP& DBP were markedly reduced by 10.99 % & 4.21, respectively, when it is followed after *Shaman Chikitsa.* Though both the groups showed statistically highly significant result., on the comparison between the two groups, it is observed that *Virechana* is more effective in reducing S.B.P. than *Vasti* Group.

6. **Agrawal R.et al. 2015**[17]

This study was conducted over 40 patients by dividing them into two groups as Group A (n=10) with Standard drug therapy(Amlodipine and Atenolol in different doses according to the severity of disease) and Group B with specific *Yoga- Asana* i.e.*Vajarasana, Makarasana& Shavasana* (each for 15 minutes+ 10 rounds of *Ekapada-Pawanamuktasana* with each leg) + *Pranayam*(3 rounds of 20 inspirations & and expirations, i.e., *Anuloma-Viloma + Bhramari*) twice a day with an empty stomach with standard drug therapy with follow-ups at the interval of 15 days.

It was found that in the Group A, there was a significant reduction in S.B.P. by 3.89% & DBP 6.82 % while significant decrease in SBP 4.19%& DBP 5.10% in the group B. Significant reduction took place in S.B.P. & DBP by 3.58% &5.16% respectively in the Group C. On the comparison between two groups. However, there were observed highly significant results for ($p<0.001$) for all subjective parameters in both groups A and B; there were found no comparable differences between two groups, especially in terms of edema and vertigo. However, highly significant results were noted in terms of headache, palpitation, easy fatigability, irritability, and insomnia.

The overall effect of treatment on symptoms was better in group B as compared to group A. At the end of the study; it was concluded that *Yogic* practice is non-pharmacological measure with proved efficacy and safety in cost effective manner. These observations signify the additive effect of selected asana and *Pranayama t*o reduce Hypertension.

7. **Manojkumar A K .et al.2016** [18]

It is a Randomized Double-Blind Clinical Trial in which 93 hypertensive patients were recruited by dividing them into three groups, i.e., n= 31 for each group. The Marsha *Nasya* with *Kaarpaasaasthyaadi Taila Mrudu Paaka, Madhyam Paka &Khara Paka* was administered to groups A.B.& C respectively for maximum 7days or up to the attainment of S*amyak Nasya Lakshana,* whichever is earlier. The daily dose of *Marsh Nasya* was between the range of 6-10 *Bindu i.e.*3-5ml for a duration of seven days Only Systolic & diastolic blood pressure was assessed after intervention for all groups.

In Group A, there was a significant increase in S.B.P. by 3.89% & DBP by 6.82%.In group B, this increased was S.B.P. by 4.19 % &DBP & 5.10%.In group C, SBP& DBP was increased by3.58% & 5.16%, respectively. Blood pressure has been shown a transient increase up to 1-2 hours after *Nasya Karma* in all groups. However, this increase was comparatively more

in group with *Nasya Karma* with *Kaarpaasasthyadi Taila Khara Paaka* than the other two groups. This increase in Hypertension was returned to normal in all groups without any medical intervention.

8. **Damodar A.et al. 2016**[19]

It was the interventional study done over 47 patients with newly diagnosed with essential Hypertension &had not been taking any kind of modern antihypertensive medicine. All patients were prescribed for *Raktadushtihar Yoga* 500 mg tablet in a dose of 2 gms twice a day with *Anupana* of water for consecutive one month. After one month, it was found that there was a significant improvement in symptoms, i.e., *Shrishula, Tamodarshana, Anidra, Bhrama, Krodhaprachutra, Tiktaamlodgar & Klama* by 86.09%, 88.51%, 74.47%, 80.80%,53.13%, 87.75%, 83.84% respectively.

There was a significant reduction in the level of S. Triglyceride, S. creatinine, alkaline phosphatase, and uric acid. In hematological parameters, only hemoglobin showed a statistically significant increase. After one month of the treatment, a 12.90% fall in systolic blood pressure was observed, whereas diastolic blood pressure was reduced by 11.19%. Both the changes were statistically significant. *Raktadushtihar Yoga* was found effective in lowering Hypertension and no change in T.L.C. Hb, R.B.C., E.S.R.

9. **Mishra D.et al.2017**[20]

It was a Randomized, Double-Blind, Clinical Study conducted in which 68 Hypertensive patients were registered. The study was planned in two groups i.e., group A (*Bramhi Vati* 500 mg) & group B (*Sarpagandha Ghana Vati* 500 mg) with water after each meal for 30 days with follow-up on every 15th days. A significant reduction was found in S.B.P. at 15th day($p<0.001$), 30th day ($p<0.001$), and 30th day ($p¼0.002$) of treatment. DBP showed a significant reduction ($p<0.001$) at both0e15th day and 30th day; however, at 15th& 30th day, improvement in group A ($p¼0.028$) and group B ($p¼0.018$) was different. Mean arterial pressure improvement in both groups was significant($p<0.001$) at both the 15th and 30th day of treatment. Improvements were also noted on the 30th day of intervention in group A ($p¼0.012$) and group B ($p¼0.005$).

Both the interventions were comparable in all secondary outcome variables when compared between the groups. However, within-group comparison showed considerable outcomes in both groups. Interventions produced significant linear improvement in Hamilton Anxiety Rating scale scores at all three-time points in both groups ($p<0.001$); significant changes were noted in pre and post comparison at total cholesterol profiles (group Aep¼0.04, group B $p<0.001$), LDL (group B $p<0.001$), sleep profiles like sleep duration (group A and Bp<0.001). Non significant improvements were observed in Sleep onset latency (group A for p= 0.05&group for ,p= 0.06). Day time drowsiness showed reduction (groupA-73.03%, group B-64.02%). Significant changes in few parameters were noted in individual groups like Hemoglobin reduction in group B (p= 0.037), serum creatinine reduction in group B ($p¼0.024$), weight gain in group A ($p¼0.007$), Body Mass Index (B.M.I.)improvement in group A ($p¼0.013$).

After this experimental study, it was found that *Brahmi Vati* was comparable to *Sarpagandha Ghana Vati* for the management of E.H.T.N. in all the aspects & both interventions were found to have *Brumhaniya, Medohara, Chittodwegahara, Nidrajanana* and antihypertensive effect.

10. Singh A.et al.2017[21]

This Clinical comparative trial was conducted over 60 patients with essential Hypertension by dividing them equally into 3 Groups, i.e., Group A with the intervention of *Chandra Avaleha* 12gms twice a day with an empty stomach with milk for 60 days, Group B with the intervention of *Yogasana (Padmasan* and *Shavasan*) and *Shirodhara* with *Mansyadi Kwath* for 60 days & Group C with all three interventions, i.e., *Chandra Avaleha, Yogasana* &*Shirodhara* simultaneously for 60 days. Patients were kept under regular diet with particular restriction of excessive salt intake, deep-fried, oily and spicy food. The follow up was taken at the interval of one week regularly for at least three weeks.

% of relief in SBP was 16.575 %, 12.756 % 19.485 % for group A,B,& C respectively it was 8.329 %, 7.205 % & 11.242 in DBP for group A,B,& C respectively. There was a reduction in serum cholesterol from 230.41 to 175.58, which was statistically significant for p-value <0.02 after intervention in all three groups.

In the group C, Headache, Dizziness, Insomnia- Anger, Slightly Body Pain with oedema, Breathlessness ,Tympanities, Anorexia, Body Stiffness, Pyrexia, Epistaxis, Palpitation, Lethargy, Tremors, chest pain & Lack of memory was reduced significantly as 84.38%, 73.33%, 60.0%, 57.50%, 85.0%, 51.81%, 66.67%, 65.0%, 45.83%, 60%, 57.14%, 47.37%, 68.75%, 50%, 52.63% &60.87% respectively. At the end of the study, it was concluded that group C with intervention of *Chandraavaleha* with *Shirodhara* and *Yogasan* was more effective than group A & B.

11. Singhal Ankur 2017[22]

In this clinical study, 44 patients of Essential Hypertension were enrolled by dividing them into two Groups (n=22 in each group). Patients in the Group A underwent for *Virechana* with *Trivrit, Haritaki, Aragvadha, Eranda* (dose of *Virechak Yoga* was decided *according to Balakostha* and *Agni* of the patient& intended for *Madhyam Shudhhi*)**.** Prior to *Virechana, Samyaka Deepan Pachana* was done by prescribing them *Chitrakadi Vati* vati500mg for five consecutive days. Then, it was followed by *Abhyantar Snehana* with *Shuddha Ghrita*(Plane cow ghee). After *Virechana, Sansarjana Karma* was advised according to the type of *Shodhana*(approx. 5-7 days)After appropriate, *Sansarjana Karma*, this group was prescribed with *Shaman Yoga,* i.e., *Bramhi, Shankhapushpi, Ashwagandha, Jatamansi, Parasikyawani, Arjun, Punarnava, Gokshur* 10gms/day in 2 divided doses for two months.

On the side, Group B was advised only *Shamana Yoga,* i.e., *Bramhi, Shankhapushpiashwagandha, Jatamansi, Parasikyawani, Arjun, Punarnava, Gokshur* 10gms in two divided doses per day for two months with salt and oil restricted diet.

After completion of the study, in the group A, there was a significant reduction in SBP&DBP by 22.01% &5.57% respectively. In comparison, there was reduction in SBP&DBP by 16.05%&18.21%respectively in the group B,. In the group A, Hemoglobin was significantly increased by 3.75% for <0.05, Serum cholesterol significantly decreased by 14.50% for P-value <0.001& Blood urea significantly reduced by 20.68% for p-value <0.05. The researchers inferred that both groups play an essential role in reducing both systolic and diastolic blood pressure. However, *Virechana Karma,* along with *Shaman Chikitsa,* offered comparatively better results in lowering the systolic and diastolic blood pressure as well as relieving cardinal and general symptoms of the patients of the Essential Hypertension than *Shaman Chikitsa* alone.

12. Rai P.et al. (2017)[23]

It is a single group clinical study done with the recruitment of 25 patients of essential Hypertension for the duration of 2 months who were advised for *Shirobhynaga* with *Bala Taila, Sarvang Abhyanga* with *Bala Taila* followed by *Takradhara* with buttermilk medicated with *Musta* and *Amalaki Churna* for 15 days regularly at morning hours for 45 minutes to one hour. Then, all these patients were further prescribed for *Sarpagandha Vati* orally for two months.

Researches concluded that symptoms of *Uchcha-Rakta-Chapa* such as *Shiroruka, Bhrama, Hriddravata, Kampa, Swasakrichhata, Alpanidra, TamoDarshana* was significantly reduced by 88.88%, 83.33%, 61.11%, 37.50%, 47.05%, 88.88% &76.92% respectively. Moreover, S.B.P. & D.B.P. was decreased significantly by 18.15% & 13.44%, respectively. Researchers quoted that *Takradhara,* along with *Sarpagandha Vati,* relieves *Uchcharakta Chapa*.

13. Pal P.et al.(2018))[24]

This comparative clinical study was conducted over 50 hypertensive patients for three consecutive months. The study population was divided into two groups(n=25 in each group). Group A (control group)was advised to undergo only *Yogic* practices(((*Nadi Shodhan Pranayam*) with *Dhyana*)& group B was prescribed for light medication of first-order initially which were withdrawn later (after 1month) along with .yogic practices). Recommended Yogic practices were advised to perform two times daily in the morning and evening regularly for three months. From Group B,(interventional group), three patients were dropped.

After completion of this study, there were statistically highly significant results in mean ± S.D. in systolic blood pressure, diastolic blood pressure, and mean blood pressure in both groups for p-value <0.001 as a reduction in ± S.D. about systolic blood pressure, diastolic blood pressure, and mean blood pressure in the interventional subgroup was 154.56±10.607, 107.52±20.157, and 117.007±6.616 that became 126.80±8.60, 95.520±6.739, and 107.48±6.199 &mean ± S.D. about systolic blood pressure, diastolic blood pressure, and mean blood pressure in control subgroup was reduced from 161.84±8.716, 98.880±5.540, and 122.59±7.534 to 148.72±9.79, 91.440±5.874, and 113.40±7.382 respectively. The researchers inferred that significant results were found in most of the symptoms of *Raktagata Vata* as well blood pressure for (p<0.001) in both subgroups, but more improvement was observed in the interventional group than control group.

14. Hari Krishnan G et al.[25]

This clinical study with a single group was conducted by enrolling 30 patients of newly diagnosed Hypertension. These patients were prescribed for *Gandharvahastadi Kashayam* 15 ml + *Ushnajala* + 1/2 *Saindhav Lavan* + *Guda b*efore food twice a day for one month regularly.

At the end of the study, Mean S.B.P. was reduced from 152.66 to 135.833 with a P-value = <0.001 & reduction in Diastolic pressure has occurred from 92.9 from 86.866 after intervention. The *Gandarvahastadi Kashayam* was also observed to be significantly effective in declining the Total cholesterol LDL & triglyceride levels for P-value <0.0001.The researcher concluded that *Gandharvahastadi Kashayam* was effective in reducing systolic B.P. and diastolic B.P.

A summary description of the essential characteristics of the included studies are as follows:

- **Type of randomization &methodology**

The number of included trials with different methodology, e.g., double-blind [18,20]. & single blind[24],etc .are mentioned in table no.1[18,20]. The type of randomization includes Computer-generated random numbers(Block method)[20], coding method[15], while the rest of the seven trials have used a Simple Random sampling technique for randomization. All trials are single centric trial.The sample size of the studies was found to be varied based on the study design adapted (a minimum sample size of 20 & 383 was the maximum sample size).

- **Inclusion-Exclusion criteria**

All these patients recruited in the studies were from the age between 15years to 70 years with irrespective of gender. 20years -65 years age group was primarily preferred in these studies up to a large extent. Hypertensive patients below 15 years and more than 70years were excluded from these 14 studies.

- **Assessment parameters**

The primary variable, SBP& DBP, were measured manually and electronic measurements in all the studies. In addition to these, M.A.P. (Mean Arterial Pressure), anthropometric measurements(B.M.I., Weight); Various biochemical & hematological parameters, (Lipid Profile, Renal profile,LFT, Blood Sugar (fasting, postprandial), & Complete C.B.C);Urine Microscopic examination;E.C.G. & X-Ray Chest were also assessed.

Among these 14 clinical trials, total 36 various symptoms of Hypertension, e.g., *Shiroruka* (Headache), *Bhrama* (Vertigo), *Hriddravata*, *Kampa* (tremors), *Swaskruchhata* (Breathlessness), *Alpanidrata* (Insomnia), *Tamodarshana, Krodhaprachurata, Tiktamlodgara, Klama,* Palpitation(*Hridspandan*), Swelling(*Urhshopha*), *Daurbalya, Urahkashtata, Pindikidweshta, Vibandha, Swedapravrutti, Urahshul* (chest pain), *Shirogaurava, Urahgaurav, Arati, Alasya* (laziness), *Akshiraga, Buddhisammoha, Santapa* (Anger), *Malavarodha, Smrutinasha, Aruchi* (Anorexia), *Hritvridhi, Tandra*(Lethargy), *Padashotha, Atimutrata.* Moreover, Epistaxis, , Tympanitis, Body Stiffness, Pyrexia were assessed as subjective variables.

Number of trials assessed with different variables e.g. with trials with only objective variables[18,22] & trials with combination of both [15,16, 19,21,23]subjective & objective variables are given in table no.2.There was no single trial that was conducted with only symptoms of Hypertension.

- **Type of intervention**

Based on the type of intervention, i.e., *Shodhana, Shamana Chikitsa,* or their combinations, studies are classified in table no.3.

Based on the intervention of specific *Shodhana u*sed, clinical studies were again sub-classified under heads as Only single therapy of *Panchakarma,* i.e., Only *Vamana*, *Virechana, Vasti,* or combinations of any two or three. There was not a single study in which only individual *Shodhana* therapy or individual *Panchakarma* therapy was used. However, there was a separate study in which effect of combinations of two procedures among *Panchkarma,* i.e., *Virechana* with *Trivrityavakut, Aragvadha, Erand, Draksha* &*Yog Basti*

Karma with alternate administration of *Anuvasan Basti* with *Dashmula Taila.& Niruha Basti* with *Makshika, Saindhav, Tila Taila, Shatapushpa, Dashmula Kwath*)was compared[16].

Based on the intervention of specific *Shamana* used, clinical studies were again sub-classified under heads as use of only herbal drugs, mineral drugs or combination, i.e., herbo-mineral drugs or Lifestyle modifications as described in table no.4:

There was not a single study conducted to assess the comparative efficacy of only herbal or herbo-mineral drugs. *Anupana p*rimarily used for these *Shamana Chikitsa* was water. In one clinical study with *Shamana Chikitsa, Raktadushtihara Yoga* with water was used as an *Anupana*(After drink).

Among all 14 clinical trials, the maximum duration of intervention was three months & the minimum period was 15 days.

- **The outcomes reported by the included studies comprised of results in Objective &Subjective parameters**

Statistically significant positive effects were reported in 02 studies assessed with Only *Shodhana Chikitsa*[16,18],07 studies assessing with *Shamana Chikitsa* (Single or combinations),04 with the combination of Both (*Shodhana* &*Shamana Chikitsa*)& 01 with Lifestyle modifications.

Statistically significant positive effects were reported due to *Shamana Chikitsa*(only herbal drugs) in 6 among the 7studies[12,15,19,20,25].

Among Subjective criteria, *Shiroruka* was the most common symptom, which was assessed in 06 studies among 14 trials & having significant relief ranging from 41.93%- 88.88%. Body Stiffness was the symptom that has got the least relief ranging from 16.13%-45.83% relief among 01 study.

S.B.P. was the most common objective variable, which was assessed in almost 14 clinical studies, which got significant relief ranging from 3.89%- 22.01%. R.B.C. was the objective variable that has got the least relief, i.e., 0.68%.

All symptoms i. e subjective variables were significantly improved with maximum extent & main objective variables, i.e., SBP& DBP, were reduced considerably almost in all studies, which was conducted with *Shodhana Chikitsa,* followed by *Shamana Chikitsa*. Intervention with a combination of *Shamana* and *Shodhana* was found to be more effective and significantly positive in all studies. It is a noteworthy thing that there was no reporting of any adverse events or side-effects of intervention.

Discussion

As Hypertension is *Bahudoshavastha Janya Vydhi,* whose pathogenesis is situated at a deeper level due to its chronicity, *Shodhana Chikitsa* remains the best option. It can also become helpful for the prevention of H.T.N. in the primary stage of the disease. *Shodhana Chikitsa* breaks the vicious cycle of metabolic dysfunction obtained in Hypertension. On the other hand, the use of *Shamana Chikitsa* is a good option for a patient who hesitates to undergo *Shodhana* procedure or person who is contraindicated for *Shodhana Chikitsa* due to any physiological or pathological conditions or co-morbidity if present. Ultimately, both

Shodhana &Shamana Chikitsa checks over the further progression of the disease by curing root cause analysis & eradicating them.

❖ **Role of *Shodhana Chikitsa***

- **Role of *Vamana***

There is no clinical evidence that can be segregated through this study to demonstrate the efficacy of *Vamana i*n Hypertension. The probable justification can be given as *Vamana* is generally contraindicated in *Hrudroga* by *Acharya Charaka* [26]. However, it can be indicated in obese persons or people with *Kapha –Medo* predominant conditions by weighing the risk-benefit ratio to induce *Apatarapana Chikitsa*[27,28]. *Vamana* decreases the peripheral resistance developed due to atherosclerotic effects by its *Kaphaghna property*. It should be contra-indicated in hypertensive patients with ischemic heart diseases or *Vataj Hrudroga.*

- **Role of *Virechana***

Virechana is highly appreciated for the management of Hypertension as the *Pitta* &*Rakta* are main *Dosha* &*Dushya,* respectively, which are highly vitiated in H.T.N. &*Virechana* is the prime *Shodhana Chikitsa* to manage them[4,22]. Moreover, as the vitiation of *Vyana Vayu* primarily takes place in hypertension &*Virechana* or *NityaVirechana* is highly appreciated by *Ayurvedic* physician to pacify it as *Mrudu Sanshodhana* is an integral part of treatment principle of *Vata Dosha*[30]. The regular elimination of vitiated *Doshas* from the body is essential to enhance the metabolism and digestive power, and this process of elimination is carried out smoothly by *Virechana* due to its diuretic action. Moreover, *Rakta Prasadakara* property of *Virechana* ultimately reduces the blood[22].

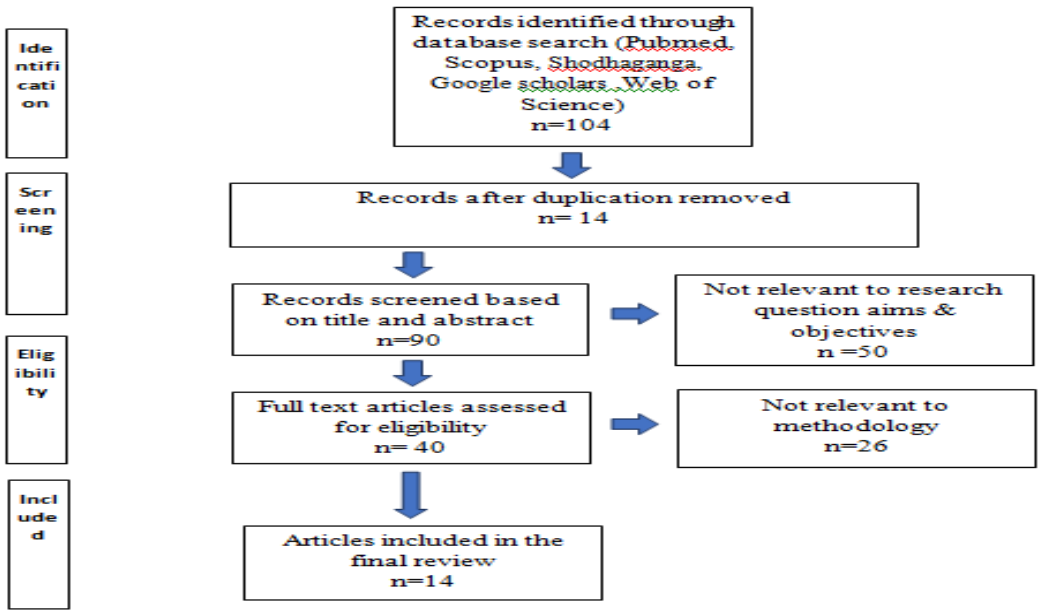
According to Manju Mohan et al. 2020, *Trivrit Churna* is effective to reduce both SBP & DBP in hypertension for the *Virechana* as it has *Madhura, Katu, Tikta, Kashaya Rasa.* Its anti-hypertensive is accentuated due to its other properties, such as *Pittakaphahara, Sukhavirechaka* nature, *Anulomana, Hrudya, Raktashodhaka, Amapachaka, Vedanasthapana,* etc. and that's why it is indicated in *Hridroga, Raktavikara, Jwara, Pleeha-yakruta Vyadhi*, etc. This laxative effect of *Trivrutta* due to the presence of turpentine in it [4].

- **Role of *Basti***

As the feedback of the vasomotor center(VMC) regulates blood pressure & administration of *Basti* activates VMC, which again enables by stimulation of sympathetic nervous system. At the same time, depression of VMC is caused by Parasympathetic stimulation, which performs vasodilatation and hence decrease in Blood pressure[16]. *Basti* is the prime treatment of vitiated *Vata* that is the pathological factors involved in hypertension. In this metanalysis, *Dashmoola Taila* is used for *Anuvasana Basti* since it is *Tridoshamaka* in nature & it reaches to rectum and colon, where it gets absorbed from colon and large intestine and break down the pathology of HTN. However, such *Anuvasana Basti* should be recommended in hypertension, having *Apatarpanajanya* origin[16].

Figure

Fig.1 : PRISMA FLOW DIAGRAM



Tables

TableNo.1: Number of trials with different types of methodology

S.N.	Type of methodology	Number of studies
1	Studies with single group	05
2	Studies with comparative groups	09
	Study with Placebo	01
	Study with no treatment	02
	Study with an anti-hypertensive agents	01
3	Open study	11
4	Single-blind Studies	01
5	Double-blind Studies	02
6	Single-center study	14

Table no.2: Number of trials with type of Assessment parameters

S.N.	Assessment parameters	Number of studies
1	Studies conducted with only Symptoms of Hypertension	-
2	Studies conducted with only objective criteria	**02**
3	Studies with combinations of both	**12**

Table No. 3:Number of trials with a specific type of intervention

S.N.	Various treatment modalities	Number of studies
1	Only *Shodhana Chikitsa*	02

2	only *Shamana Chikitsa* including Lifestyle modifications :	07
3	Combination of both *Shodhana* & *Shamana Chikitsa*	05

Table No. 4:Number of trials with specific type of *Shamana Chikitsa*

S.N.	***Shamana Chikitsa***	**List of Drugs**	**Number of studies**
1	Only herbal drugs	*Bramhi Vati, Sarpagandha Vati, Raktaduhtihar yoga, Gokshura Ghana Satva, Saptaparna Kwath, shankhapushpyadi ghana Vati, Gandharvahastadi Kashaya saindhav, guda*	06
2	Only mineral drugs	-	00
3	Only herbo-mineral drugs	-	00
4	Only Lifestyle modifications :	02 (Yogic practices (*Nadi Shodhan Pranayam*) and *Dhyana,* lifestyle modifications and hypertensive protocol)	01

❖ **Role of *Shamana Chikitsa***

Bramhi Vati is a compound formulation that has action to reduce blood pressure due to its cardiac depressive, anti ischemic& diuretic nature. It is useful to fall blood pressure in stress-induced Hypertension due to its anxiolytic, anticonvulsive, antioxidant, anti-arrhythmic & calcium inhibitory effects. On the other hand, *Sarpagandha Vati* has antihypertensive property due to its essential component, i.e., reserpine, which depresses the C.N.S. and PNS by binding to catecholamine storage vesicles. It acts by CB1 receptors in brain PNS & A.N.S. & ultimately becomes helpful to fall B.P[2].

Gokshura antagonizes the pathogenesis of Hypertension by reducing the intravascular volume, accumulation of fluid, and further contents of blood pressure like renal, C.N.S., Cardiac, endocrine system by its best diuretic action and *Vatahara* property[12].

Hypertension is *Kapha* predominant disorder due to *Santarapanjanya Hetu*. *Saptaparna Kashaya* helps to reduce the blood pressure in hypertensive cases originated from atherosclerotic plaques. *Saptaparna Kashaya* induces this antihypertensive effect due to its *Kapha* pacifying effect by its *Kashaya & Tikta Rasa*, *Katuvipaka, Ushna Virya* and *Snigdha* and *Sara Guna*. Moreover, it removes the obstruction & induces *Srotoprasarana* due to its *Vatanulomak &Agnidipti* properties[13].

As the essential Hypertension is *Vatapitta* predominant *Tridoshaja Vyadhi,* therefore, *Mrudu-Virechana* induces antihypertensive effect. *Gandharavahastadi Kashaya* produces a similar *Mrudu Virechak* effect due to its properties such as *Vatashamaka, Agnivardhaka, Ruchya, Malashodhaka*[25].

Raktdushtihar Yoga induces purification and nourishment of *Rakta Dhatu* due to its *Raktaprasadak* and *Raktashodhana* properties. The antihypertensive effect of this yoga is further enhanced by its two essential ingredients, i.e., *Musta* and *Katuka,* which reduces cholesterol and triglycerides[19].

Generally, therapies like *Shirodhara* with *Bramhi Taila, Nasya, Takradhara, Yoga* is an ancient therapy that can be used for the treatment of Hypertension, mainly if it is originated from stress. All these procedures induce tranquilizer effects by maintaining mental function intact & sound. *Yoga* stabilizes the body-mind complex, which is very important in the patho-physiology of Hypertension and its cause. *Pranayam, Asanas, Dhyana* can give excellent results with the *Shaman or Shodhan Chikitsa*[17]. Yogic practices at the region of *Agnya Chakra*, the person can develop t capability of shifting of involuntary actions to voluntary of changing of sympathetic to parasympathetic via developing a psychological control over cerebrothalamo limbic system and reduction in Sign and symptoms of *Raktagata Vata* [24].

Only Lifestyle modifications (regular physical activity, reduced intake of salt or sodium, increase intake of potassium supplement, and avoidance of alcohol, more intake of vegetables and fruits, milk products with a lower proportion of fat, reduction of cholesterol, and saturated fat in meals) are generally recommended to prevent the Hypertension as it reduces the body weight in case of obesity [31,9] .

The strict inclusion of R.C.T.s is the strength of this systematic review. The current literature review study also collated evidences regarding the efficacy & safety of the integrative & rational approach of both *Shodhana* & *Shamana Chikitsa* for the management of Hypertension. In some studies, intervention for a short duration with a small sample also demonstrated quick significant results over symptoms of Hypertension as well as its objective variables such as SBP& DBP. Other related studies on hypertension are available[32,33].

On an extensive review of *Shodhana Chikitsa* in Hypertension, it is observed that not a single study is conducted showing the efficacy of *Vamana* or *Raktamokshana* in reducing blood pressure. Though *Rakta* & *Pitta* are main *Dushya* & *Dosha*, respectively, involved in Hypertension & *Raktamokshana* can play an essential role in HTN due to its *Rakta Prasadkara* Property & *Pitta Virechana* effect. However, considering this lacunae, further studies should be encouraged to plan in the future. Moreover, it is also noticed that, though the overall effect of *Shodhana t*herapy, including *Virechana, Vasti* was discussed. Still, the individual mode of action of *Shodhana* drugs used for that was not elaborated in any trial, which demands to plan studies showing comparative effectiveness of different *Shodhana.* Therefore, based on their inferences, appropriate selection of *Shodhana Dravyas* can be made in clinical practice to get maximum output of therapies in HTN.

Conclusion:

The current systemic review explored all available *Ayurvedic* trials with pharmacological(*Shamana &Shodhana Chikitsa*) and non- pharmacological intervention(Lifestyle & Yoga practices) in Hypertension &verified their effectiveness and safety. This study proves that rational use of *Ayurvedic* interventions can successfully manage H.T.N. in primary stage or newly diagnosed cases. Moreover, these interventions also showed their supportive or adjuvant role with contemporary treatment protocol.

Future clinical studies with a large sample size for longer duration are expected in the future to conduct to fulfill the above shortcomings of the previous studies & to observe their sustained effects. However, strict monitoring of such trials is necessary.

NOTE:

The study highlights the efficacy of " Ayurvedic " which is an ancient tradition, used in some parts of India. This ancient concept should be carefully evaluated in the light of modern medical science and can be utilized partially if found suitable.

COMPETING INTERESTS DISCLAIMER:

Authors have declared that no competing interests exist. The products used for this research are commonly and predominantly use products in our area of research and country. There is absolutely no conflict of interest between the authors and producers of the products because we do not intend to use these products as an avenue for any litigation but for the advancement of knowledge. Also, the research was not funded by the producing company rather it was funded by personal efforts of the authors.

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