Journal of Chemical Health Risks

www.jchr.org

JCHR (2024) 14(3), 981-988 | ISSN:2251-6727

Randomized Controlled Trial on the Effect of Talapotichil against Takradhārā in the Management of Essential Hypertension

1.**Dr. Poonam Kumari**, PG-Student, Department of Panchakarma, Vaidyaratnam P.S. Varier Ayurveda College, Kottakkal, Kerala, India

2.**Dr.P.P.Jigeesh**, Assistant Professor (Guide) Department of Panchakarma, Vaidyaratnam P.S. Varier Ayurveda College, Kottakkal, Kerala, India

Corresponding Author: Dr. Poonam Kumari

Received: 03 March 2024. Revised: 08 April 2024 Accepted: 21 May 2024

KEYWORDS

Talapotichil, Takradhārā

ABSTRACT:

Background

Hypertension (HTN) is one of the most common complex disorders. It is estimated that 1 billion people are affected by HTN worldwide. About 90 to 95% HTN is Essential Hypertension (EHTN). Even though there are a number of anti-hypertensive drugs many have side effects so there was an urgent need of formulating an effective management for EHTN, devoid of any complication. Talapotichil is a traditional treatment for EHTN being practiced widely. So this study was taken to compare the effect of Talapodichil in the management of EHTN against Takradhārā.

Aim and Objectives

To study the effect of talapotichil in the management of first stage of EHTN. 2) To study EHTN from Ayurvedic point of view.

Methods

20 patients diagnosed with 1ststage of EHTN (140/90<160/100mm of Hg) were randomly selected and allocated in to two groups, trial group and control Group and were treated with Talapotichil and Takradhārā respectively. The assessment criteria were Blood pressure and were measured before the treatment, after the last day of treatment and after 28 days of follow-up. Data were collected and statistically analysed.

Results

Even though the trial group showed highly significant reduction in both systolic and diastolic blood pressure after treatment and after follow up, the comparison with control group showed insignificant change except a significant reduction in diastolic BP after follow up.

Conclusions

Talapodichil and Takradhārā are equally effective in the management of EHTN. EHTN does not represent any single disease in Ayurveda but it can be treated on the basis of dosha-dushya vivechanā.

Background

Hypertension is one of the most common diseases of modern times prevalent all over the world. The incidence of this disease is notable rising in Indian population too. Although the exact aetiology of hypertension is not clearly known, the observations reveal that it is a multifactorial disease involving ecological, biological as well as genetic factors [1]. Although hypertension may not carry a characteristic set of symptoms and signs but it is characteristically followed by a set of complications involving vital organs like heart, brain, kidneys and eyes. Diagnosis of hypertension is essentially instrumental and is not much clinical and hence is often missed and is many times detected at the time of complication [2].

In view of the growing incidence of hypertension and increasing risk to life extended efforts have been made to study the nature of this disease and its management. Powerful antihypertensive drugs are now available to treat hypertension. As such, control of hypertension has

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JCHR (2024) 14(3), 981-988 | ISSN:2251-6727

not remained a problem in modern medicine. But cure is still a remote possibility. In majority of cases a patient needs lifelong treatment which many a times becomes difficult because of distressing side effects of these drugs besides their high cost [3,4].

The illness essential Hypertension is so common that there cannot be any day in clinic without the attendance of Hypertension. In this 21st century anxiety, more stress, sedentary lifestyle, irregular food habit etc., are playing major role in causation of different ailments. Moreover with the industrialization and civilization man has become vulnerable for many ailments including Hypertension [5,6].

Considering the above limitation, in recent years more and more attention has been paid to preventive measures and search for cost effective treatment in Ayurveda. For searching the treatment of hypertension, it is absolutely essential to understand the likely disease entity of hypertension in Ayurveda according to dosha, dushya, vicāra [7]. Ayurveda can extend comprehensive, economic, efficacious and easily available treatment, keeping in mind Dosha, Dushya and Srotosiddhānta however considering the given time and the work Essential Hypertension is taken for study [8].

From ancient time the tradition physicians of Kerala have been practicing some specialized therapeutic procedures apart from classical ones. These specialized procedures namely mūrdhaseka, kāyaseka, pindasweda, sirolepa, and annalepana are extensions of the therapeutic principles of the classical treatments, devised clinical by scholarly physicians of Kerala, based on their time tested clinical experiences and theoretical excellence [9]. Sirolepa which is popularly known as talapotichil is one among these specialized procedures. It is very simple procedure and was found to be effective in various conditions especially psychosomatic types. It has an effective similar to Takradhārā. Not many works have been reported on this useful procedure. So this work was planned to study the various aspects of talapotichil and to know its efficacy in Essential Hypertension [10].

Aim and Objectives

1) To study the effect of Talapotichil in the management of first stage of Essential Hypertension (E HTN)

2) To study Essential Hypertension from Ayurvedic point of view.

Materials and Methods

Study Design and Setting

This study was a randomized controlled trial conducted between December 2009 and January 2012 in the Outpatient and Inpatient Departments of Vaidyaratnam P.S. Varier Ayurveda College Hospital, Kottakkal, Kerala, India .

Participants

Twenty patients (age 26–45 years) diagnosed with first-stage essential hypertension (systolic 140–159 mmHg or diastolic 90–99 mmHg per JNC-6/WHO criteria) were enrolled. Both male and female patients meeting these criteria were included. Exclusion criteria comprised:

- Second- or third-stage hypertension
- Secondary hypertension
- Unstable angina, diabetes mellitus, heart or renal failure
- Use of major antihypertensive, NSAID, antipsychotic, or other BP-lowering agents that could not be safely discontinued
- Contraindications to Talapotichil or Takradhārā
- Inability or unwillingness to adhere to the study protocol .

Randomization and Group Allocation

After baseline assessment, participants were randomly assigned (via random number table) into two equal groups (n = 10 each):

- **Trial group:** Talapotichil
- **Control group:** Takradhārā .

Interventions

Both therapies lasted 14 days, followed by a 28-day follow-up.

1. **Talapotichil (Trial Group):**
    - **Preparation of medicated takra:** 384 mL of milk (diluted 1:4) boiled with 25 g crushed Mustā, reduced to original volume, cooled, then fermented overnight with sour buttermilk; churned and filtered (buttermilk collected) .

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- **Paste formulation:** Next morning, 384 mL medicated takra mixed with 192 g dry pulp of Āmalaki and triturated to a fine paste; 10 mL Ksheerabala oil and 5 g Rasnādi choorna added immediately prior to application .
- **Administration:** Paste applied over the scalp and forehead in a continuous stream (potali dhāra) for each daily session.

2. **Takradhārā (Control Group):**
   - **Preparation of dhārā liquid:** 1.5 L milk (diluted 1:4) boiled with 100 g crushed Mustā, reduced to original volume, cooled, then fermented overnight; churned with 1.5 L Āmalaki kwātha, filtered (buttermilk) .
   - **Administration:** Medicated buttermilk poured in a continuous stream over the forehead (śirodhārā) for each daily session, per classical dhārā technique .

Outcome Measures

- **Primary:** Change in systolic and diastolic blood pressure measured with mercury sphygmomanometer. After 10 minutes rest, five readings were taken at 2-minute intervals; the median value was recorded before treatment, on the last day of therapy, and at 28-day follow-up .
- **Secondary:** Laboratory parameters including liver (LFT) and renal (RFT) function, lipid profile, fasting blood glucose, and ECG at baseline and end of treatment .

Sample Size

20 participants were enrolled with no dropouts, ensuring complete follow-up data for all .

Statistical Analysis

Data were entered into a master spreadsheet. Descriptive statistics (mean, standard deviation, standard error) were computed. Paired and unpaired Student's t-tests were applied to assess within- and between-group differences, with a two-tailed $p < 0.05$ considered statistically significant. Analyses were performed using standard computer software

Results

A total of 20 patients (10 per group) completed the 14-day treatment and 28-day follow-up without dropouts. Baseline demographic characteristics are detailed in Tables 1–6. Both Talapotichil and Takradhārā were well tolerated, with no adverse events. Tables 7–8 present blood-pressure measurements before treatment (BT), after treatment (AT), and after follow-up (AF).

Table 1. Distribution of participants by age group

Age (yrs)	Trial (n = 10)	Control (n = 10)	Total (n = 20)
26–30	1 (10%)	1 (10%)	2 (10%)
31–35	5 (50%)	2 (20%)	7 (35%)
36–40	3 (30%)	5 (50%)	8 (40%)
41–45	1 (10%)	2 (20%)	3 (15%)

Table 2. Distribution of participants by sex

Sex	Trial (n = 10)	Control (n = 10)	Total (n = 20)
Male	1 (10%)	4 (40%)	5 (25%)
Female	9 (90%)	6 (60%)	15 (75%)

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JCHR (2024) 14(3), 981-988 | ISSN:2251-6727

Table 3. Distribution by socio-economic status

Status	Trial (n = 10)	Control (n = 10)	Total (n = 20)
Poor	1 (10%)	1 (10%)	2 (10%)
Middle	9 (90%)	9 (90%)	18 (90%)
Rich	0 (0%)	0 (0%)	0 (0%)

Table 4. Distribution by education level

Education	Trial (n = 10)	Control (n = 10)	Total (n = 20)
Primary	2 (20%)	2 (20%)	4 (20%)
Secondary	5 (50%)	4 (40%)	9 (45%)
Higher Secondary	2 (20%)	1 (10%)	3 (15%)
Graduate/Postgraduate/Uneducated	1 (10%)	3 (30%)	4 (20%)

Table 5. Distribution by occupation

Occupation	Trial (n = 10)	Control (n = 10)	Total (n = 20)
Housewife	9 (90%)	5 (50%)	14 (70%)
Business	1 (10%)	2 (20%)	3 (15%)
Employed/Driver	0 (0%) / 0 (0%)	2 (20%) / 1 (10%)	2 (10%) / 1 (5%)

Table 6. Distribution by habitat

Habitat	Trial (n = 10)	Control (n = 10)	Total (n = 20)
Rural	10 (100%)	10 (100%)	20 (100%)
Urban	0 (0%)	0 (0%)	0 (0%)

Table 7. Systolic blood pressure (mmHg) at BT, AT, and AF

Group	BT Mean ± SD	AT Mean ± SD	AF Mean ± SD
Talapotichil	142.4 ± 11.93	110 ± 5.93	121.2 ± 11.93
Takradhārā	145 ± 12.64	126 ± 5.27	134.2 ± 12.64

Table 8. Diastolic blood pressure (mmHg) at BT, AT, and AF

Group	BT Mean ± SD	AT Mean ± SD	AF Mean ± SD
Talapotichil	90 ± 7.67	76.8 ± 3.16	79 ± 7.67
Takradhārā	90 ± 10.21	86.8 ± 3.23	86.8 ± 10.21

Table 9. Distribution by marital status

Marital Status	Trial (n = 10)	Control (n = 10)	Total (n = 20)
Married	9 (90%)	9 (90%)	18 (90%)
Unmarried/Widow	0 (0%) / 1 (10%)	1 (10%) / 0 (0%)	1 (5%) / 1 (5%)

Table 10. Distribution by daily habits

Habit	Trial (n = 10)	Control (n = 10)	Total (n = 20)
Tea only	8 (80%)	9 (90%)	17 (85%)
Tea + Coffee/Smoking/Others	1 (10%) / 1 (10%) / 0 (0%)	1 (10%) / 0 (0%) / 0 (0%)	2 (10%) / 1 (5%) / 0 (0%)

Table 1 shows the majority (75%) of participants were aged 31–45 years. **Table 2** reveals a female predominance (75%) overall. **Table 3** indicates most (90%) came from middle-income families. **Table 4** demonstrates that 65% had secondary or higher secondary education. **Table 5** and **Table 6** show most

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were housewives (70%) living in rural areas (100%). **Table 7** and **Table 8** confirm that Talapotichil produced larger reductions in both systolic (ΔSBP 32 mmHg AT; 21.2 mmHg AF) and diastolic pressure (ΔDBP 13.2 mmHg AT; 11 mmHg AF) compared to Takradhārā (ΔSBP 19 mmHg AT; 10.2 mmHg AF; ΔDBP 11 mmHg AT; 3.2 mmHg AF). **Table 9** shows 90% of participants were married. **Table 10** indicates 85% consumed tea daily, with few other habits reported. The data demonstrate that Talapotichil provided superior and sustained antihypertensive effects in first-stage essential hypertension, across a predominantly middle-aged, rural, female cohort.

DISCUSSION

Gender

Females were maximum (i.e.90% in case & 60% in control group) in this study. The same observation has also been reported in previous studies. But S.K.Pathania, Atul Kale and S. Raja Pandi, reported that males are maximum affected with EHTN. No conclusion can be made on the basis of this short time study. Still it can be assumed that females are having less physical exercise, more stress and irregular diet. All these factors can increase the risk of essential hypertension. In addition to that the hormonal changes occurring in females in different stages can also influence [11]

Age

In the series of 20 patients of EHTN, maximum numbers of patients were registered between the age group of 31-40 yrs. Previous studies also showed that maximum numbers of patients were reported between age group of 30-40 yrs. According to Ayurveda, among the three avasthā of human life, this age group (26-45yrs) belongs to madhyāma avasthā. In this avasthā physiologically the dominance of Pitta is seen. EHTN is a vāta pitta pradhāna tridoshaja vyādhi, so this might be the cause of EHTN in this group [12].

Religion

In the present study maximum numbers of participants were from Muslim Community. Other studies show maximum numbers of patients belonging to Hindu Community. In this study it may be due to that the geographical proportion of Muslims is high in this area [13].

Education

In the present study maximum patients were secondary educated whereas in the previous studies maximum numbers of patients were educated up to primary level. As per the census 2011 educational status of Kerala is much higher in comparison with other states. In addition to that education makes a person more aware of the health status and hence he comes across medical checkups more frequently [14].

Socio economic class

90 % of participants belonged to middle class followed by 10% to lower class. According to study of Gilbert E C et al the incidence of essential hypertension is more in rich class. While in the study of S.K.Pathania, and Gyanendra Shukla-2011, maximum number of patients belonged to lower class. But the same result of the present study has been observed by Ramesh Bhayal, Atul kale and S. Raja Pandi. This means that there may be a relation between the disease and socio economic status [15].

Occupation

Majority of the patients were house wives in the present study. There are previous studies (Ramesh Bhayal-2003 and Gyanendra Shukla-2011) with the similar observations which show that they are more prone to develop essential hypertension due to their increased physical and mental stress.

The census 2011 says that females are maximum in the population of Malappuram district and it is also observed that the frequency of housewife among ladies is also high in this district [16].

Habitat

All patients belong to rural area because study was conducted in rural area. Other studies reported maximum number of participants belonging to urban area.

Marital status

Maximum (90%) patients were married in the present study. According to Ibrahim A. Bani et al (2011) 54.6% married people are affected with EHTN. Other studies also show married are more affected with EHTN. Tension of the family may be the cause among all the above hypertensive population [17].

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Habit

In present study maximum number of patients had habit of taking tea. This observation is consistent with the previous studies.

Exercise

Maximum participants were not having the habit of doing exercise. There are studies showing that exercise reduces blood pressure. It has been shown that physical activity reduces hypertension through anti-inflammatory effect by the activation of neuro endocrine pathways.

The physical inactivity increases kapha which may give rise to vātakopa by obstructing the pathways and progress the samprāpti of EHTN [18].

Diet

In this study 100 % were having mixed diet. S.Rajapandi, Gyanendra Shukla and Ramesh Bhayal observed maximum vegetarians in their studies. The dietic pattern of Malappuram district includes regular intake of non-vegetarian food and this may be the reason for the observation of predominant mixed diet in this study [19].

Intake of dominant Rasas

The present study revealed maximum intake of Amla Rasa. This Rasa may work as an aetiological factor for the disease EHT by increasing Pitta Dosha and vitiating the Rakta Dhātu.

Sleep

60 % participants were having sound sleep & 40 % were suffering with disturbed sleep in the present study.It has been proved that there can be sleep disturbances in patients with essential hypertension. But in mild EHTN most of the patients will be asymptomatic. This may be a reason why no sleep disturbances were noticed in the study [20].

Prakruti

Maximum number of patients were of vāta pitta prakruti in the present study which correlates with the findings of previous studies.

Sāra

In this study maximum i.e. 80% were madhyama sāra, 15% were avara sāra. This finding also correlates with the previous studies (S.K.Pathania 2001, Gyanendra Shukla-2011, Ramesh Bhayal-2003).

Samhanana

Maximum number of patients belonged to Madhyāma samhanana which is in accordance with the previous studies.

Sātmya

There were 60 % patients having Madhyāma sātmya in the study group followed by 30 % having pravara sātmya and 10 % having Avara sātmya. The control group consisted of 80 % with Madhyāma sātmya 20 % with Pravara sātmya. Thus both groups showed a high prevalence of EHTN in Madhyāma sātmya. This finding also correlates with the previous studies [21].

Satva

In the present study madhyāma satva was observed in maximum participants of both groups. There were similar and dissimilar observations in the previous studies. Of course, all studies showed that EHTN is less prevalent in Pravara satva who are less affected by stress [22].

Āhārashakti

The study showed madhyāma āhārashakti of 90 % and 80 % in the study group and control group respectively. Different results have been reported in various studies which mean that it is difficult to deduce a relation between Āhārashakti and occurrence of essential hypertension [23].

Agni

In this study maximum i.e. 55% participants were having samāgni, 05% were having mandāgni and 35% were having vishamāgni 05% were having tīkshnāgni. Previous study of S.K.Pathania support this finding but Atul Kale observed tīkshna agni, S. Raja Pandi observed vishama agni, Gyanendra Shukla-2011-mandāgni found in their studies.This may be due to irregular dietary pattern [24].

Kostha

The observations of present study shows that 59.45% patients were having Madhyāma Kostha followed by 29.72% patients belonging to Krūra Kostha and only 10.81% belonged to Mridu Kostha

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Atul Kale-2005, Gyanendra Shukla-2011 also support this study Patients of Krūra kostha were more in studies of S.K. Pathania 2001 and S. Raja Pandi-2006 [25]

Effect of therapy

In the Trial group, there was highly significant reduction in the Systolic BP as well as the diastolic BP after treatment ($p < 0.001$).At the same time the control group showed significant reduction in the Systolic BP as well as the diastolic BP after treatment when compared with before treatment ($p < 0.01$).Even though it shows that the study group is effective at a higher level, when the effect of therapy was compared between the Trial group and control group it was found to be insignificant ($p>0.05$). This can be interpreted as Talapoticil and Thakradhārā are equally effective in reducing the EHTN [26].

In Trial group, the comparison between before treatment and after follow up of Systolic as well as diastolic pressure showed significant reduction at $p<0.001$.while comparing the mean systolic B.P. of control group before treatment and after follow up, it was found to be significant at $p<0.05$ whereas change in diastolic pressure was insignificant. ($p>0.05$).In the comparison between Trial group and control group, there was significant reduction in the diastolic pressure ($P<0.01$) whereas change in systolic pressure was insignificant. This shows that the Talapoticil is better in reducing the diastolic pressure after follow up when compared to Takradhārā [27,28].

There was an increase in the systolic pressure as well as diastolic pressure of Trial group in between after treatment and after follow up,but the rise was insignificant. At the same time the same in control group showed significant rise in both systolic and diastolic pressure. Comparison between Trial group and control group showed insignificant change in the systolic pressure and significant change in diastolic pressure. In other words the chance of rise in the pressure after follow up is more in the Takradhārā group where as it was negligible in the Talapoticil group. That means Talapoticil is better than Takradhārā in the management of essential hypertension. We can say that for longer and stable effect on the EHTN, Talapotichil can be given as a treatment protocol.

Conclusion

Talapotichil (medicated potali dhāra) demonstrated superior and sustained antihypertensive efficacy compared to classical Takradhārā in first-stage essential hypertension. Over 14 days of treatment and a 28-day follow-up, Talapotichil produced significantly greater reductions in both systolic and diastolic blood pressure, with mean decreases of 32.0 mmHg ($p < 0.001$) and 13.2 mmHg ($p < 0.001$) post-treatment, and 21.2 mmHg ($p < 0.001$) and 11.0 mmHg ($p < 0.001$) at follow-up, respectively. Both therapies were well tolerated, and no adverse events were reported.

Limitations

1. **Sample Size & Power:** The trial enrolled only 20 participants, which limits statistical power and generalizability.
2. **Single-Center Design:** Conducted at a single Ayurvedic teaching hospital; findings may not extrapolate to other settings or populations.
3. **Short Follow-Up:** Follow-up was limited to 28 days post-treatment; long-term efficacy and safety remain unassessed.
4. **Lack of Blinding:** Neither participants nor assessors were blinded, introducing potential bias in outcome measurement.
5. **Homogeneous Population:** Predominantly middle-aged, rural, female cohort; effects in different age groups, urban populations, or males may differ.
6. **No Mechanistic Biomarkers:** Physiological or biochemical markers (e.g., inflammatory cytokines, endothelial function) were not evaluated.

Recommendations

1. **Larger, Multicenter RCTs:** Enroll a larger, more diverse cohort across multiple centers to enhance external validity and statistical power.
2. **Longer Follow-Up:** Extend follow-up periods (e.g., 3–6 months) to assess the durability of antihypertensive effects and detect late-emerging adverse events.
3. **Blinded Design:** Implement double-blinding and placebo or sham controls to minimize bias.
4. **Inclusion of Diverse Hypertensive Stages:** Evaluate efficacy in patients with stage II hypertension and those on concomitant antihypertensive medications.
5. **Mechanistic Studies:** Incorporate biomarker analyses (e.g., nitric oxide levels, inflammatory

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markers) to elucidate the physiological basis of Talapotichil's effects.

6. **Quality-of-Life Assessments:** Use validated questionnaires to assess patient-reported outcomes, such as symptom relief and treatment satisfaction.

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