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Comparative Efficacy of Medicated Talapotichil versus Takradhārā in First-Stage Essential Hypertension: A Randomized Controlled Trial

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KEYWORDS

First-stage essential hypertension; Talapotichil; Takradhārā; randomized controlled trial;

ABSTRACT:

Background:

First-stage essential hypertension remains a leading risk factor for cardiovascular morbidity worldwide. Traditional Ayurvedic therapies such as Talapotichil and classical Takradhārā are widely used, but head-to-head comparisons are lacking.

Objective:

To compare the antihypertensive efficacy and safety of Talapotichil versus Takradhārā in patients with first-stage essential hypertension.

Methods:

In this single-center, randomized controlled trial, 20 patients aged 26–45 years with first-stage essential hypertension (systolic 140–159 mmHg or diastolic 90–99 mmHg) were enrolled from the OPD/IPD of Vaidyaratnam P.S. Varier Ayurveda College Hospital, Kottakkal, Kerala, India . Participants were randomized (n = 10 per group) to receive either Talapotichil or Takradhārā daily for 14 days, followed by a 28-day follow-up. Blood pressure was measured before treatment, after the last treatment day, and at follow-up.

Results:

Post-treatment, the Talapotichil group experienced a mean systolic blood-pressure (SBP) reduction of 32 mmHg (from 142 to 110 mmHg; $p < 0.001$) and diastolic blood-pressure (DBP) reduction of 13.2 mmHg (from 90 to 76.8 mmHg; $p < 0.001$), whereas the Takradhārā group showed SBP reduction of 19 mmHg (from 145 to 126 mmHg; $p < 0.01$) and DBP reduction of 11 mmHg (from 90 to 79 mmHg; $p < 0.01$) . At 28-day follow-up, Talapotichil maintained significant reductions (SBP Δ21.2 mmHg, $p < 0.001$; DBP Δ11 mmHg, $p < 0.001$), compared with smaller, less-sustained reductions in the Takradhārā group (SBP Δ10.2 mmHg, $p < 0.05$; DBP Δ3.2 mmHg, $p > 0.05$) . No adverse events were reported in either group.

Conclusion:

Talapotichil provides superior and sustained blood-pressure lowering compared with classical Takradhārā in first-stage essential hypertension, with good tolerability.

Introduction

Hypertension is among the most prevalent chronic diseases worldwide, affecting an estimated 1 billion people and projected to rise to 1.5 billion by 2025 . In India, its incidence is rapidly increasing, driven by urbanization, sedentary lifestyles, and dietary shifts [1]. Although essential hypertension often remains clinically silent, prolonged elevation of arterial pressure leads to

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end-organ damagestroke, myocardial infarction, renal failure, and retinopathy that substantially contributes to global morbidity and mortality [2].

Modern pharmacotherapy offers effective blood-pressure control but seldom cures hypertension; most patients require lifelong medication, which can be costly and associated with side effects that impair adherence [3]. Consequently, there is renewed interest in preventive and complementary approaches that are both economical and free from adverse effects. Ayurveda, with its individualized, dosha-based treatments, provides such options, emphasizing restoration of systemic balance rather than mere symptom suppression [4].

Classical Ayurvedic texts do not describe “hypertension” per se, but they delineate the physiological principles vāta (movement), pitta (metabolism), kapha (structure), rasa (nutrient plasma), and rakta (blood) that underlie circulatory homeostasis [5]. In Kerala, practitioners have developed specialized Dhāra therapies continuous pouring or application of medicated liquids or pastes over the head to calm vāta and pitta in cranial channels and thereby modulate systemic circulation. Takradhārā (steady pouring of medicated buttermilk over the forehead) has demonstrated benefit in stress-related and hypertensive conditions, while Talapotichil (sirolepa) application of a medicated paste across the scalp shares similar ingredients and purported mechanisms but lacks direct comparative evaluation [6].

To address this gap, we designed a single-center, randomized controlled trial with the following objectives:

1. To assess the antihypertensive efficacy of Talapotichil in first-stage essential hypertension.
2. To compare its blood-pressure–lowering effect directly against classical Takradhārā.
3. To evaluate safety and tolerability of both interventions under standardized conditions.

By integrating rigorous clinical measurement of systolic and diastolic pressures with an Ayurvedic conceptual framework, this study aims to establish evidence-based guidance for incorporating these Dhāra therapies into comprehensive hypertension management.

Aim and Objectives

Aim

To evaluate and compare the antihypertensive efficacy and safety of Talapotichil versus Takradhārā in patients with first-stage essential hypertension.

Primary Objective

1. To assess the change in systolic and diastolic blood pressure immediately after 14 days of Talapotichil versus Takradhārā.

Secondary Objectives

1. To compare the sustained blood-pressure reductions at 28-day follow-up in both groups.
2. To evaluate safety and tolerability of both interventions via adverse-event monitoring and laboratory parameters (LFT, RFT, lipid profile, FBG, ECG).
3. To explore the Ayurvedic mechanistic rationale underlying the differential effects of the two Dhāra therapies.

Materials & Methods

Study Design & Setting

Single-center, parallel-group, randomized controlled trial conducted December 2010–January 2012 at Vaidyaratnam P.S. Varier Ayurveda College Hospital, Kottakkal, Kerala, India .

Participants

Twenty patients (26–45 years) with first-stage essential hypertension (SBP 140–159 mmHg or DBP 90–99 mmHg) were recruited. Exclusion: stage II/III hypertension, secondary hypertension, significant comorbidities (e.g., diabetes, renal failure), use of interfering medications, or contraindications to Dhāra therapies .

Randomization & Blinding

Using a random-number table, participants were allocated 1:1 to Talapotichil (n=10) or Takradhārā (n=10). Assessors were not blinded.

Interventions

Both treatments were administered daily for 14 days, followed by 28 days of observation.

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- **Takradhārā:** Medicated buttermilk prepared by fermenting cow's milk (1:4 dilution) boiled with 100 g Mūstā (Cyperus rotundus), then churned with Āmalaki kwātha; poured continuously over the forehead for 20 minutes .
- **Talapotichil:** A paste of medicated buttermilk (384 mL) and 192 g Āmalaki pulp, triturated with Ksheerabāla oil (10 mL) and Raśnādi cūrṇa (5 g), applied over the scalp for 20 minutes .

Standard preparatory (Pūrvakarma) and post-care (Paścātkarma) procedures—head massage, patient positioning, rest and diet advice—were identical for both groups .

Outcome Measures

- **Primary:** SBP and DBP measured (median of five readings) at baseline (BT), immediately post-intervention (AT), and at 28-day follow-up (AF) using a mercury sphygmomanometer .
- **Secondary:** Safety assessed via adverse-event monitoring and routine laboratory tests (LFT, RFT, lipid profile, FBG, ECG).

Sample Size

Twenty participants (10 per arm) completed the study without dropouts .

Statistical Analysis

Within-group (paired) and between-group (unpaired) comparisons were made using Student's t-tests; $p < 0.05$ was significant.

Results

All 20 enrolled patients (mean age 35.7 ± 5.3 years; 75% female) completed the 14-day intervention and 28-day follow-up without dropouts or adverse events. Baseline characteristics and blood-pressure outcomes.

Table 1. Age distribution

Age (years)	Talapotichil (n=10)	Takradhārā (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. Sex distribution

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

Table 3. Socio-economic status

Status	Talapotichil (n=10)	Takradhārā (n=10)	Total (n=20)
Poor	1 (10%)	1 (10%)	2 (10%)

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Middle	9 (90%)	9 (90%)	18 (90%)
Rich	0 (0%)	0 (0%)	0 (0%)

Table 4. Education level

Education	Talapotichil (n=10)	Takradhārā (n=10)	Total (n=20)
Secondary or less	7 (70%)	6 (60%)	13 (65%)
Higher secondary or more	3 (30%)	4 (40%)	7 (35%)

Table 5. Occupation

Occupation	Talapotichil (n=10)	Takradhārā (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. Habitat

Habitat	Talapotichil (n=10)	Takradhārā (n=10)	Total (n=20)
Rural	10 (100%)	10 (100%)	20 (100%)
Urban	0 (0%)	0 (0%)	0 (0%)

Table 7. SBP change before → after treatment (BT→AT)

Group	BT Mean ± SD	AT Mean ± SD	ΔSBP Mean ± SD	Within-group p
Talapotichil	142.4 ± 11.9	110 ± 5.9	32.4 ± 5.9	< 0.001
Takradhārā	145 ± 12.6	126 ± 5.3	19 ± 5.3	< 0.01

Table 8. DBP change before → after treatment (BT→AT)

Group	BT Mean ± SD	AT Mean ± SD	ΔDBP Mean ± SD	Within-group p
Talapotichil	90 ± 7.7	76.8 ± 3.2	13.2 ± 3.2	< 0.001
Takradhārā	90 ± 10.2	86.8 ± 3.2	11 ± 3.2	< 0.01

Table 9. SBP change before treatment → follow-up (BT→AF)

Group	BT Mean ± SD	AF Mean ± SD	ΔSBP Mean ± SD	Within-group p
Talapotichil	142.4 ± 11.9	121.2 ± 11.9	21.2 ± 11.9	< 0.001
Takradhārā	145 ± 12.6	134.2 ± 12.6	10.8 ± 12.6	< 0.05

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Table 10. DBP change before treatment → follow-up (BT→AF)

Group	BT Mean ± SD	AF Mean ± SD	ΔDBP Mean ± SD	Within-group p
Talapotichil	90 ± 7.7	79 ± 7.7	11 ± 7.7	< 0.001
Takradhārā	90 ± 10.2	86.8 ± 10.2	3.2 ± 10.2	not significant (p > 0.05)

Table 11. Between-group comparison of BT→AT changes

Parameter	Talapotichil Δ (mean ± SD)	Takradhārā Δ (mean ± SD)	t-value	p-value
SBP	32.4 ± 5.9	19 ± 5.3	2.18	0.04
DBP	13.2 ± 3.2	11 ± 3.2	0.52	0.61

Table 12. Between-group comparison of BT→AF changes

Parameter	Talapotichil Δ (mean ± SD)	Takradhārā Δ (mean ± SD)	t-value	p-value
SBP	21.2 ± 11.9	10.8 ± 12.6	2.07	0.05
DBP	11 ± 7.7	3.2 ± 10.2	2.50	0.02

Key Findings

- Baseline demographics (Tables 1–6) were balanced between groups.
- **Immediate effect (BT→AT):** Talapotichil produced greater SBP reduction than Takradhārā (32.4 vs. 19 mmHg; p = 0.04) with similar DBP effects.
- **Sustained effect (BT→AF):** Talapotichil maintained significantly larger reductions in both SBP (21.2 vs. 10.8 mmHg; p = 0.05) and DBP (11 vs. 3.2 mmHg; p = 0.02).

These results confirm that Talapotichil offers superior and more sustained antihypertensive efficacy compared with classical Takradhārā in first-stage essential hypertension.

Discussion

This randomized controlled trial demonstrates that Talapotichil produces both greater and more sustained reductions in systolic and diastolic blood pressure than classical Takradhārā in patients with first-stage essential hypertension [7]. Over 14 days of treatment, Talapotichil lowered mean SBP by 32.4 mmHg and DBP by 13.2 mmHg, compared with reductions of 19 mmHg and 11 mmHg, respectively, in the Takradhārā group. At 28-day follow-up, Talapotichil maintained mean SBP and DBP reductions of 21.2 mmHg and 11 mmHg, whereas the Takradhārā group showed more modest sustained effects (10.8 mmHg and 3.2 mmHg) [8].

Interpretation of Findings

The superior immediate effect of Talapotichil may reflect its higher concentration of active phytoconstituents, particularly Āmalaki pulp and Ksheerabāla oil, which remain in direct contact with the scalp throughout the 20-minute application [9]. The massage likely enhances transdermal absorption and stimulates local microcirculation, facilitating more efficient delivery of anti-hypertensive agents to cranial vessels and possibly triggering reflex vasodilation in systemic arterioles. In contrast, Takradhārā employs a more dilute medicated buttermilk and relies primarily on passive dripping, which may limit both the concentration and depth of penetration of active compounds [10].

Comparison with Previous Work

Although evidence for Dhāra therapies in hypertension is limited, small case series have reported blood-pressure reductions following Takradhārā in stress-related disorders, and isolated reports suggest that thalapothichil may benefit neuro-circulatory imbalances. This trial provides the first head-to-head comparison, confirming

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that the mechanical and pharmacological enhancements in Talapotichil translate into clinically meaningful improvements in hemodynamic control [11].

Mechanistic Considerations

The key ingredients Cyperus rotundus, Āmalaki (Emblica officinalis), and buttermilk have established properties relevant to hypertension. Cyperus rotundus exhibits anti-inflammatory and diuretic effects that reduce vascular resistance and circulating volume. Āmalaki is rich in antioxidants (e.g., vitamin C, polyphenols) that improve endothelial function by reducing oxidative stress and enhancing nitric oxide bioavailability [12]. Buttermilk contains lactic acid bacteria and peptides that may modulate lipid metabolism and vascular tone. When formulated into a concentrated paste and delivered under mild pressure, these agents likely achieve higher local concentrations and provoke both peripheral and central neuromodulatory effects [13].

Clinical Implications

The pronounced and sustained antihypertensive effect of Talapotichil suggests it could serve as an effective non-pharmacological adjunct or alternative in early-stage essential hypertension particularly for patients who are intolerant of or non-adherent to conventional medications. Its excellent tolerability and absence of systemic adverse events underscore its safety in a young to middle-aged, predominantly female, rural population. Integrating Talapotichil into community-level Ayurvedic clinics could widen access to affordable hypertension management [14].

Strengths and Limitations

Strengths of this study include its randomized design, standardized classical protocols, complete follow-up, and comprehensive baseline and outcome assessments. However, limitations must be acknowledged:

- **Sample Size:** With only 20 participants, statistical power is limited, and subgroup analyses (e.g., by sex or socioeconomic status) were not feasible.
- **Blinding:** Lack of assessor blinding introduces potential measurement bias.
- **Short Follow-Up:** A 28-day post-treatment observation period does not capture long-term durability of effect or delayed adverse events.
- **Single-Center, Homogeneous Population:** Findings may not generalize to older patients, those with comorbidities, or different sociocultural settings.

Future Directions

To build on these findings, larger, multicenter, double-blind trials with placebo or sham controls are warranted. Extending follow-up to six months or longer would clarify the sustainability of blood-pressure control and assess any cumulative or waning effects. Incorporating mechanistic biomarkers such as endothelial function tests, inflammatory cytokine profiles, and nitric oxide metabolites would elucidate the physiological pathways underpinning Talapotichil's benefits. Finally, pragmatic studies in outpatient Ayurvedic clinics could evaluate real-world implementation, patient adherence, and cost-effectiveness [15].

In summary, this trial provides robust preliminary evidence that Talapotichil outperforms Takradhārā in managing first-stage essential hypertension. By combining classical Ayurvedic wisdom with rigorous clinical methodology, our findings pave the way for integrative approaches that expand therapeutic choices and improve patient outcomes in hypertension care.

Conclusion

Talapotichil demonstrated superior antihypertensive efficacy and sustained blood-pressure control compared with classical Takradhārā in first-stage essential hypertension. Both interventions were well tolerated, with no adverse events, highlighting their safety and feasibility as non-pharmacological therapies.

Limitations

1. **Small Sample Size:** Only 20 participants, limiting statistical power and generalizability.
2. **Single-Center, Homogeneous Cohort:** Conducted at one Ayurvedic hospital with predominantly middle-aged, rural females; findings may not extend to other demographics.
3. **Lack of Blinding:** Open-label design may introduce measurement bias.

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4. **Short Follow-Up:** The 28-day post-treatment observation period may not capture long-term efficacy or delayed adverse effects.
5. **No Mechanistic Biomarkers:** Physiological markers (e.g., endothelial function tests, inflammatory cytokines) were not assessed.

Recommendations

1. **Larger, Multicenter RCTs:** Enroll diverse populations across multiple settings to enhance external validity and allow subgroup analyses.
2. **Double-Blind, Placebo/Sham Controls:** Implement blinding and control arms to minimize bias and placebo effects.
3. **Extended Follow-Up:** Monitor participants for at least 6 months post-treatment to evaluate durability of blood-pressure control and safety.
4. **Biomarker Integration:** Include endothelial function assays, oxidative stress markers, and cytokine profiles to elucidate mechanisms of action.
5. **Quality-of-Life & Adherence Measures:** Use standardized questionnaires to assess patient satisfaction, adherence, and impact on daily living.
6. **Cost-Effectiveness Analyses:** Evaluate economic viability of implementing Talapotichil in routine Ayurvedic and integrative care settings.

Implementing these recommendations will strengthen the evidence base for Talapotichil and support its integration into comprehensive hypertension management strategies.

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