



RESEARCH ARTICLE

CLINICAL PILOT STUDY ON VASAMBU CHOORANAM FOR THE MANAGEMENT OF
KURUTHI AZHAL NOI (PRIMARY HYPERTENSION)

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ABSTRACT

Siddha is a complete holistic medical system that has been widely practiced in India and Sri Lanka. Hypertension is the most common cardiovascular disease and is a major public health issue in developed as well as developing countries. Approximately 20% of the world's adults are estimated to have hypertension. In Siddha medicine, symptoms of "Raththa kothippu noi" comes under the "Kuruthi azhal noi" is resembles as hypertension. In Siddha text many herbs or Herbal formulation has been mentioned to treat the Kuruthi azhal noi (Hypertension). In this view, the Vasambu chooranam is also indicated for Kuruthi azhal noi. The aim of the study was to evaluate the safety and efficacy of "Vasambu chooranam" on Kuruthi azhal noi. This study was conducted at the OPD of Ayothidoss Pandithar Hospital, National Institute of Siddha, Tambaram Sanatorium, Chennai-47 on 20 patients with Kuruthi azhal noi (Primary hypertension) who were satisfied the inclusion criteria. The dose of the Vasambu Chooranam was 1g with warm water, twice a day, before meals for 4 weeks. Blood pressure was monitored on subsequent following visit at 7th 14th 21st and 28 days respectively. End of the of drug treatment data analysis was carried out using Bonferroni post Hoc test by GraphPad Prism 5.0. At the first visit the mean baseline systolic blood pressure, the mean diastolic blood pressure and the mean arterial blood pressure (MAP) were 150.00 mmHg, 93.80 mmHg and 113 mmHg respectively. The mean value of these parameters SBP, DBP and MAP decreased to 135 mmHg, 86.40mmHg and 103 mmHg respectively at end of study. There was significant reduction in systolic blood pressure, diastolic blood pressure and mean arterial blood pressure (P value < 0.0001). "Vasambu Chooranam" is effective in treating the mild to moderate Kuruthi azhal noi (Hypertension) with positive outcome on the quality of life.

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INTRODUCTION

Siddha system is considered to be one of the ancient systems of medicine in the world. Siddha is a complete holistic medical system that has been widely practiced in India and Sri Lanka. The Siddha system of medicine has derived its name from the word "Siddhi" which means "Perfection" or "Eternal bliss". Siddhi refers to the eight supernatural powers that are attainable by man. Those who attained these supernatural or Siddhi were called "Siddhars". They realized that if the body could be made strong and perfect, they could get free of death and diseases (Kayakatpam). It is well founded on the basic principle of nature and its elements after a careful and thorough study of the human system (Uthamaroyan, 2001). Pancha bhutha theory has also been described by Siddhars. The Pancha bhuthas are Akayam (space), Kaattru (air), Thee (fire) Neer (water) Nilam (earth). In the universe each and every form of substances has been made by Pancha bhuthas

simultaneously human body consist of five basic elements, seven physical constituents and the three humours Vali (tsp), Azhal (moy;), Iyam (Iak;) are the three main physiological regulators of the body and mind. They are called "Muththathukkal". They remain always in a state of equipoise in healthy individuals. Increase or decrease of one or more will cause disease (Shanmugavelan, 1992).

“மிகிலும் குறையிலும் நோய்செய்யும் நூலோர்வனிமுதலா எண்ணிய முன்று”

The equilibrium of tri humors is considered as health and its disturbance or imbalanced leads to a diseased state, Saint Thiruvalluvar stated his Thirukural. Hypertension is a significant and common health problem because of the percentage of the population affected and the serious consequences of uncontrolled high blood pressure. Hypertension (HTN) or high blood pressure (BP) is a chronic medical condition in which the BP in the arteries is elevated. It is classified as either primary (essential) or secondary. About 90 to 95% of cases are termed primary HTN, which refers to

high BP for which no medical cause can be found (Carretero *et al.*, 2000). The remaining 5 to 10% of cases, called secondary HTN, are caused by other conditions that affect the kidneys, arteries, heart, or endocrine system (Beevers *et al.*, 2001). Hypertension is currently defined in terms of levels of blood pressure associated with increased cardiovascular risk. A cut-off of 140/90 mm Hg is accepted as a threshold level above which treatment should at least be considered. This would give a prevalence of hypertension of about 20% of the adult population in most developed countries 6(a). Hypertension is a major risk factor for myocardial infarction (heart attacks), stroke, heart failure, aneurysms of the arteries, peripheral arterial disease and is a cause of chronic kidney disease and retinopathies. Even modest elevation of arterial blood pressure (i.e. 150/95) is associated with a shortened life expectancy⁷.

Hypertension results from the complex interaction of genetic factors and environmental influences. Many of the genetic factors remain to be discovered, but environmental influences such as salt intake, diet and alcohol form the basis of no pharmacological methods of blood pressure reduction. The main determinants of blood pressure are cardiac output and peripheral resistance. The typical hemodynamic finding in patients with established hypertension is of normal cardiac output and increased peripheral resistance 6 (b). High blood pressure (BP) is a major risk factor for cardiovascular and renal complications. A majority of treated hypertensive patients still complain of high BP. The renin-angiotensin aldosterone system (RAAS) has been a centre-stage target for all the cardiovascular and cardio-renal complications⁸. The coexistence of renal arterial vascular (ie, renovascular) disease and hypertension roughly defines this type of nonessential hypertension. More specific diagnoses are made retrospectively when hypertension improves after intravascular intervention⁹. Control of the cardiovascular diseases will require modification of risk factors that have two characteristics. First, the risk factor must have high attributable risk or high prevalence or both, and secondly, most or all of the risks must be reversible cost-effectively¹⁰. Aggressive treatment of hypertension in multiple-risk populations (to the goals of JNC VI and the recent WHO-ISH Guidelines for the Management of Hypertension) can be expected to produce significant reductions in the incidence and prevalence of stroke, heart failure, coronary heart disease, chronic renal failure, and total cardiovascular mortality¹¹. It was estimated that around two-thirds of those with people with hypertension worldwide were living in developing countries (639 million) in 2000, and that this would rise to three-quarters living in developing countries (1.15 billion) by 2025 (Sushil *et al.*, 2012). About 75 to 80% of the world population use herbal medicines, mainly in developing countries, for primary health care because of their better acceptability with human body and lesser side effects. In the last three decades, a lot of concerted efforts have been channeled into researching the local plants with hypotensive and antihypertensive therapeutic values¹³.

In Siddha literature "Noi nadal and Noi mudhal nadal thirattu" the disease "Raththa kothippu noi" comes under the "Kuruthi azhal noi" which can be easily compared with hypertension in modern medicine. The symptoms of Hypertension is resembles as Kuruthi azhal noi, so Kuruthi azhal noi may be correlated with Hypertension. In Siddha text many herbs or Herbal formulation has been used to treat Kuruthi azhal noi (Hypertension). In this view the Vasambu chooranam is also

indicated for hypertension. So the researcher selected the drug "Vasambu chooranam" to evaluate the safety and efficacy on Kuruthi azhal noi.

MATERIALS AND METHODS

Identification and Collection of Plant Material

The rhizome of *A. calamus* was procured from local market of Chennai, Tamil Nadu, India. It was identified, authenticated by (Asst.Prof.Dr.Aravinth) Department of Medicinal Botany, National Institute of Siddha, Chennai and voucher specimen certificate number NISMB 151204.

Method of Purification & Preparation of Trial drug

The classical method the sample of Rhizomes were covered by turmeric paste and allowed for fully dried in sunshade after that it was taken in to the vessels and fried until burn finally it was fine powdered and stored in an airtight container. This study was conducted at the OPD of Ayothidoss Pandithar Hospital, National Institute of Siddha, Tambaram Sanatorium, Chennai-47.IEC approved number is NIS/IEC/8-14/40. Patients with *Kuruthi azhal noi* (Primary hypertension) who were satisfied the inclusion criteria. Informed consent was taken from the patients before including the trial.

Sample size: 20patients

Study period: 06 months

Subject selection

Inclusion criteria:

Age : 35-60 years
Sex : Both male & Female
Weight : 40-90 kgs
Patients of Primary Hypertension having
BP Systolic 120-159 mm /Hg
BP Diastolic 80-99 mm /Hg

Exclusion criteria

- Secondary Hypertension with any organ damage like retinopathy or renal dysfunction, so it can be avoided from inclusion criteria.
- Hypertension in Pregnancy
- Hypertension associated with
 - Stroke
 - Diabetes mellitus

Ischemic heart disease (Already ruled out by ECG)

- Drugs (NSAIDS, Oral contraceptive pills)
- Alcohol abuse
- Obesity

Withdrawal Criteria

1. Acute conditions Sudden severe elevation of BP (Systolic B.P>200/Diastolic B.P>120)
2. Irregular follow up
3. Adverse drug reaction.

4. Non co-operative patients
5. In case of Emergency

Investigation/assessment: All the 20 patients were investigated symptomatically.

Trial drug and duration

Drug: *Vasambu Chooranam* - 1g with luke warm water, twice a day, before meals.

Duration of the treatment: 4 weeks.

Conduct study

Kuruthi azhal noi (Primary hypertension) patients satisfying inclusion and exclusion criteria were recruited to the trial. Informed consent was obtained from the patients. Routine investigations like Blood test and urine test were carried out before and after the trial treatment. For Out patients the trial drug was issued for 4 weeks course. They were advised to visit the OPD once in 7 days. At each visit they were clinically assessed.

Statistical Analysis

Data analysis was carried out using Bonferroni post Hoc test by GraphPad Prism 5.0, Statistical significance was accepted as $p < 0.05$

RESULTS

At the first visit the mean baseline systolic blood pressure, the mean diastolic blood pressure and the mean arterial blood pressure (MAP) were 150.00 mmHg, 93.80 mmHg and 113mmHg respectively. The mean value of these parameters SBP, DBP and MAP decreased to 135mmHg, 86.40mmHg and 103 mmHg respectively at end of the study. There was significant reduction in systolic blood pressure, diastolic blood pressure and mean arterial blood pressure (P value < 0.0001). The results were shown in Figure -01

Systolic, Diastolic and Arterial Blood Pressure

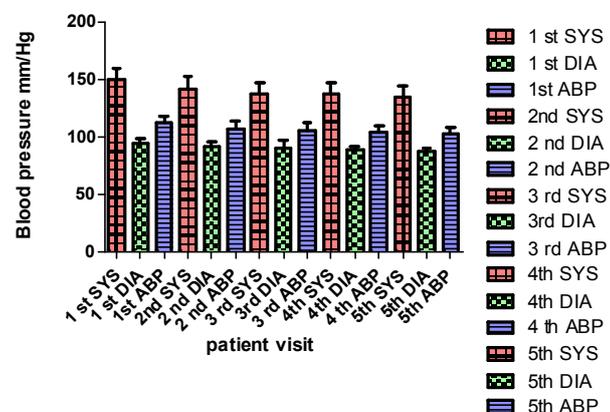


Figure 1.

DISCUSSION

The drug *Vasambu chooranam* was selected to find out the Anti-hypertensive activity in the management of *Kuruthi azhal noi* (primary Hypertension), the literary evidence from the text

Gunapadam Mooligai Vagupu and quality standards of Indian medicinal plants strongly supports the Anti-hypertensive activity of the drug. This observation could possibly justify the usefulness of the *Vasambu chooranam* is clinical effective to reduce Systolic and diastolic blood pressure for further validation number of patients should be increased.

Conclusion

“Vasambu Chooranam” is effective in treating the mild to moderate hypertension associated with co-morbid conditions with positive outcome on the quality of life.

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