

**A PILOT STUDY ON “COMBINATION OF SIDDHA FORMULATION”
IN THE TREATMENT OF “VALI AZHAL KEEL VAYU”
(RHEUMATOID ARTHRITIS)**

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ABSTRACT

Objective: The present study is to evaluate the clinical effectiveness of the combination of *Siddha* drugs (*Seenthil chooranam* and *Serankottai nei*) in the treatment of *Vali Azhal Keel Vayu*. **Methods:** The study was carried out in the Out-Patient Department(OPD) and In-Patient Department(IPD) of the Ayothidoss Pandithar Hospital, National Institute of Siddha as an open labelled pilot study. In a study period of 12 months, 20 patients of either sex were selected for a clinical trial of 48 days. 10ml of *Merugulli thylam* was taken orally with hot milk as a purgative medicine on the first day of treatment followed by two days of medicated rest. 2gm of *Seenthil chooranam* with lukewarm water and 10 drops of *Serankottai nei* with hot milk were taken orally, twice

daily for 45 days. The clinical effectiveness of the trial drugs was assessed by using DAS28 score before and after the treatment. **Result and Discussion:** Out of 20 patients, 85% of the patients showed a significant reduction in joint pain and swelling and have a good improvement in their joint movements. The data were analyzed statistically and the result showed significant ($p < 0.05$) improvement in the treatment of *Vali Azhal Keel Vayu*. Hence this combination of drugs is effective in the treatment of *Vali Azhal Keel Vayu*.

KEYWORDS: *Siddha* medicine, Rheumatoid arthritis, *Vali Azhal Keel Vayu*, *Seenthil chooranam*, *Serankottai nei*.

INTRODUCTION

Siddha is a holistic medical system that gives importance to physical as well as mental well-being of an individual. *Siddhars* have listed the diseases of mankind as 4448 based on the derangement of *Uyirhathukkal* i.e., *Vali*, *Azhal* and *Iyyam*.^[1] As per *Yugi* and *Theraiyar*, excessive intake of bitter, pungent and astringent foods, altered sleep rhythm, excessive walking in summer, frequent fasting and more weight bearing are mentioned as the causes for *Vatha* diseases. The *Vatha* diseases are classified into 80 types as mentioned in the text '*Yugi Vaidhiya Chinthamani*'. *Vali Azhal Keel Vayu* (VAKV) is one among them and the signs and symptoms of this disease is correlated with Rheumatoid arthritis.

Rheumatoid arthritis (RA) is the chronic inflammatory disease affecting the joints and other parts of the body occurring throughout the world and in all ethnic groups. It is an autoimmune disease, which causes inflammation in the synovial membrane of the joints. Symmetrical involvement of joint pain, swelling and early morning stiffness are the primary clinical manifestation. The arthritis usually begins in the small joints of the hands and the feet, spreading later to the larger joints.^[2] The clinical course is prolonged, with intermittent remissions and exacerbations. Over a period of time it can affect other organs and systems throughout the body, from heart, lungs, skin and blood vessels.

About 1% of the world's population are affected by rheumatoid arthritis, women three times more often than men. The incidence of RA is about 3 cases per 10,000 populations per annum. Onset is uncommon under the age of 15 and from then on the incidence rises with age until the age of 80.^[3] In India a local survey in Delhi shows the prevalence of this disease affecting 0.75% of population.^[4]

At NIS hospital, the number of VAKV patients is gradually increasing. Many *Siddha* formulations are being prescribed to treat this disease. According to the *Siddha* literature, the ingredients of the selected formulations are indicated for the symptoms of pain, morning stiffness and swelling.

Here I have chosen the combination of *Siddha* formulations *Seenthil chooranam* and *Serankottai nei* which are available in our hospital OPD and IPD for the study.

MATERIALS AND METHODS

Trial drugs^[5]

1. *Merugulli thylum* - 10ml on the first day of treatment for purgation
2. *Serankottai nei* - 10 drops, bid, after food with warm milk
3. *Seenthil chooranam* - 2 gm, bid, after food with warm water

Study Design

It was an open label, non-comparative, Interventional pilot study. The study protocol and related documents were reviewed and approved by Institutional Ethics Committee (IEC) at the National Institute of Siddha, Chennai- 47, India.

The IEC approval number is **NIS/IEC/2011/3/13a-24/12/2011**. The trial was registered in Clinical Trial Registry India (**CTRI/2013/12/004203**). The study was conducted in the Ayothidoss Pandithar Hospital, National Institute of Siddha, Chennai 47. Patients with the symptoms of VAKV reporting to the NIS hospital were subjected to screening by screening Proforma. After screening they were enrolled for the study based on the inclusion and exclusion criteria. 20 Patients of either sex were included in the study. Before enrollment the patients were informed about the study, trial drug, possible objectives and outcomes of the study in their vernacular language. After ascertaining the patient's willingness, informed consent was obtained in written form.

Inclusion Criteria

- Age: 20- 60 years
- Sex: Both male and female
- Symmetrical joint involvement
- Arthritis of two or more joints
- Morning stiffness.
- Swelling, especially in the inter-phalangeal joint.
- Patients willing for admission and stay in IPD or willing to attend OPD
- Patients willing to undergo Radiological investigation and for laboratory investigation.
- Patients willing to sign the informed consent stating that he/she will consciously stick to the treatment during 48 days and the patients can opt out of the trial of his/her own conscious discretion.

Exclusion Criteria

- Pregnancy and lactation
- Osteoarthritis
- Gouty arthritis
- Any other serious systemic illness

Conduct of the Study

Patients who satisfied the inclusion and exclusion criteria were subjected to the clinical trial. Patient's informed consent was obtained. OPD patients were asked to visit the hospital once in 7 days. At each visit clinical assessments were performed and trial drugs were provided. For IPD patients, the clinical assessment was done daily in the ward and trial drugs were given daily. The results were compared at the end of the study. Laboratory investigations, radiological investigations and DAS28 score were done before and after the treatment.

All enrolled subjects were assigned to a single group and were given 10ml of *Merugulli thylam* orally for purgation on the first day of treatment, followed by two days of medicated rest. From the 4th day, 2gm of *Seenthil chooranam* with lukewarm water and 10 drops of *Serankottai nei* with hot milk was given orally, twice daily for the next 45 days. Recruited patients were advised to carry on their daily activities and exercises that they had been doing before the enrollment and also advised to continue the same till the end of the study period. At the end of the treatment, the patients were advised to visit the OPD for follow-up for further 2 months for observing any recurrence.

Study Assessment

The improvement of the clinical conditions was assessed on the basis of the improvement in pain, swelling, physical function of the joints, comparison of laboratory investigations, radiological investigations and DAS28 score was done before and after the treatment.

DAS28

Disease Activity Score of 28 joints (DAS28) is widely used as an indicator of RA disease activity and response to treatment, but is not always a reliable indicator of treatment effect. The number of joints with tenderness upon touching (**TEN28**) and swelling (**SW28**) are counted. In addition, the Erythrocyte sedimentation rate (**ESR**) is measured. Also, the affected person makes a subjective assessment (**SA**) of disease activity during the preceding 7

days on a scale between 0 and 100, where 0 is "no activity" and 100 is "highest activity possible". With these parameters, DAS28 is calculated as;

$$DAS28 = 0.56 \times \sqrt{TEN28} + 0.28 \times \sqrt{SW28} + 0.70 \times \ln(ESR) + 0.014 \times SA$$

From this, the disease activity of the affected person can be classified as follows,

Current DAS28		DAS28 decrease from initial value		
		≥ 1.2	> 0.6 but ≤ 1.2	≤ 0.6
≤ 3.2	Inactive	Good improvement	Moderate improvement	No improvement
≥ 3.2 but ≤ 5.1	Moderate	Moderate improvement	Moderate improvement	No improvement
> 5.1	Very active	Moderate improvement	No improvement	No improvement

Statistical Analysis

The results of all the patients enrolled in this clinical trial were analyzed by Student's paired t-test. The changes in the various clinical parameters and DAS28 score done before and after the treatment were analyzed and summarized in the result column. Statistical significance was considered at the 95% confidence interval level. P values ≤ 0.05 were considered statistically significant and were expressed as Mean \pm standard deviation (Mean \pm SD).

RESULTS AND DISCUSSIONS

Rheumatoid arthritis is an autoimmune disease that primarily affect the joints and result in pain, swelling and restricted movement in that joint. Chronic inflammation of rheumatoid arthritis can cause permanent joint destruction and deformity. Rheumatoid arthritis is also referred as systemic illness, because it can also involve inflammation of tissues in other areas of the body, such as lungs, heart and eyes. There is no cure for this disease. Treatment involves a combination of patient education, rest, exercise, joint protection and medication. Medication used in the treatment of Rheumatoid arthritis include NSAID (Non-steroidal anti-inflammatory drug), Corticosteroids and DMARDs (Disease-modifying anti-rheumatic drugs).^[6,7] The use of medicinal plants is becoming popular due to the adverse effect of these NSAID's, corticosteroids and DMARD's. *Siddha* system of medicine has rich collection of herbs possessing anti-arthritic properties. Herbal drugs are believed to enhance the natural resistance of the body against infection and their immune-modulatory activities have been reported in numerous plants.

According to *Siddha* system, *Vali Azhal Keel vayu* (Rheumatoid arthritis) is caused due to the derangement of *Vali* and *Azhal* humour. Treatment is mainly aimed at balancing these elevated humours (mukuttram) through Purgation and Medication. This is done because of

the *Siddhars* saying “*Viraesanathal vatham thalum*” which means, by purgation *vatham* is normalised. Therefore 10ml of *Merugulli thylam* was given orally with hot milk as a purgative medicine on the first day of treatment. 2gm of *Seenthil chooranam* with lukewarm water and 10 drops of *Serankottai nei* with hot milk were given orally, twice daily for the next 45 days. The individual ingredients of *Seenthil chooranam* possess immunomodulatory^[8], anti-inflammatory, analgesic, antipyretic, antioxidative, hepatoprotective and neuroprotective activities^{[9],[10],[11]} and *Serankottai* has anti-inflammatory, antioxidative, antirheumatic, antiatherogenic, neuroprotective activities.^[12] which further proves the efficacy of these two drugs for Rheumatoid arthritis.

Following are the important observations made from this study. 20 patients came with the symptoms of pain, swelling, tenderness and morning stiffness. 12 of these patients had restricted movements and 8 patients had fever. Das28 score was done before and after the treatment. After 48 days of treatment all the clinical signs and symptoms of patients were reduced which is illustrated in Chart (4). The data were analysed statistically and the result showed significant ($p < 0.05$) improvement in the treatment of *Vali Azhal Keel Vayu* which is illustrated in table (1). Further details like age, gender wise distribution and family history were also showed in chart 1, chart 2 and chart 3. The result of this study proves that the combination of *Seenthil chooranam* and *Serankottai nei* are effective in the treatment of Rheumatoid arthritis.

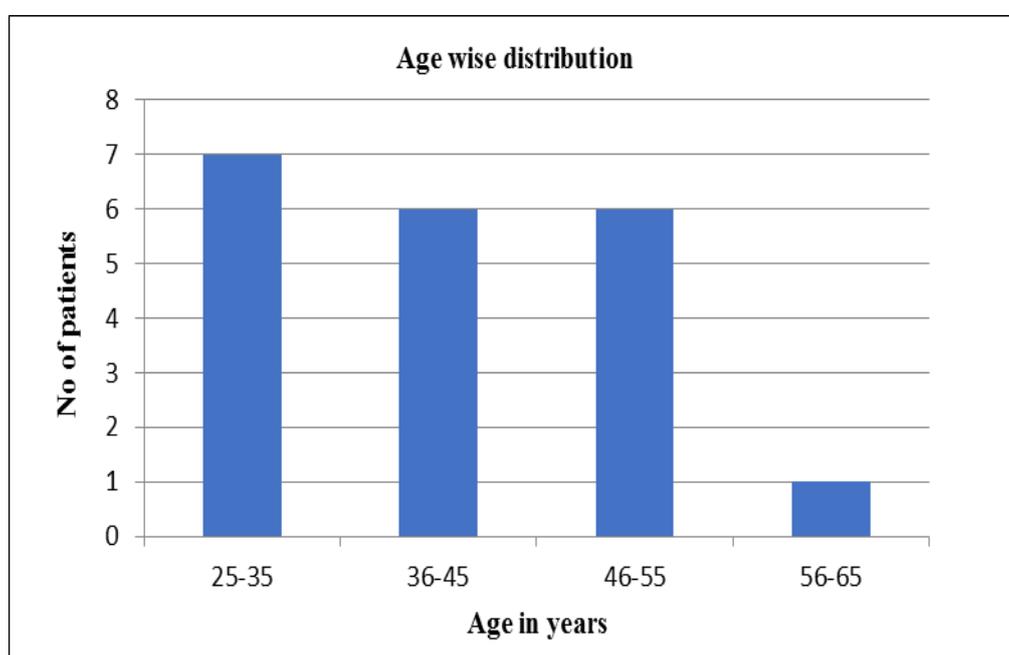


Chart 1: Age wise distribution chart of VAKV patients.

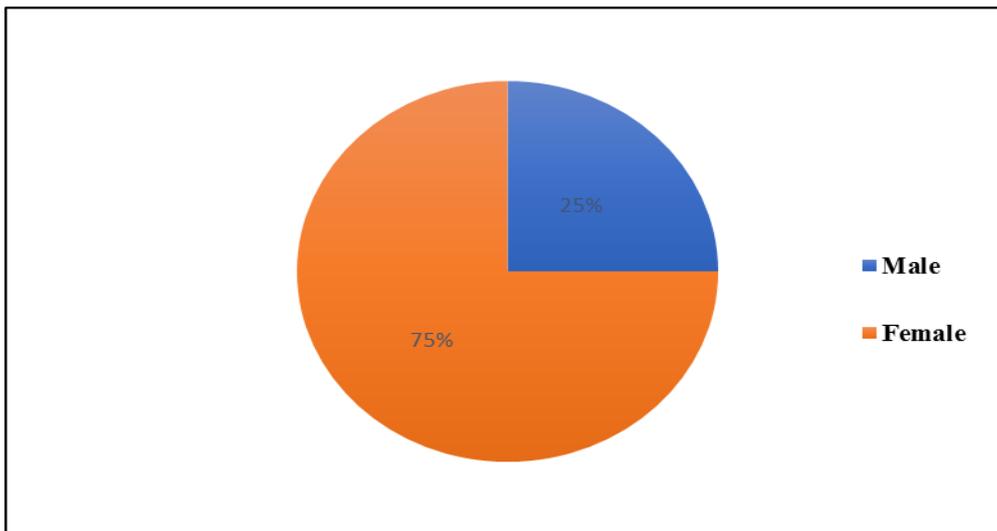


Chart 2: Gender wise distribution chart of VAKV patients.

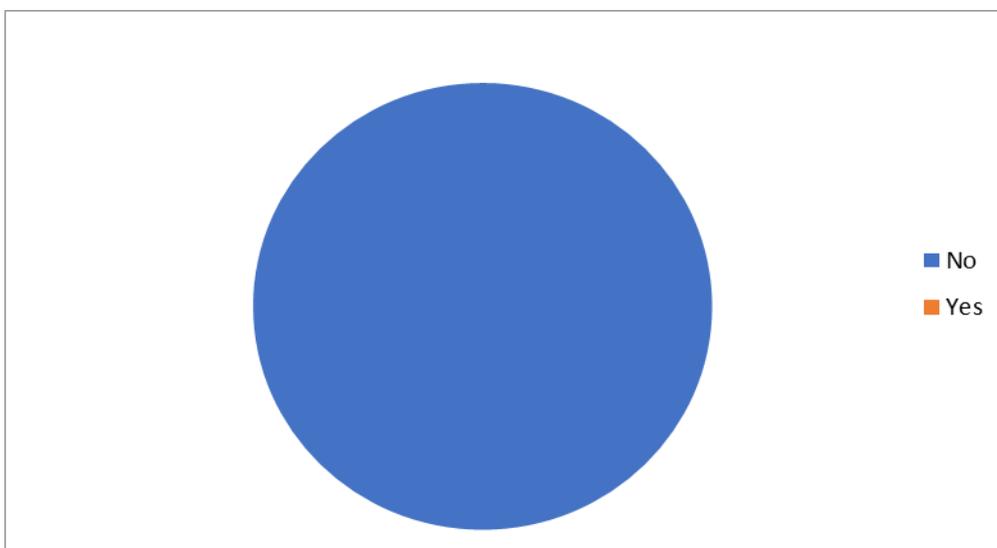


Chart 3: Family history chart of VAKV patients.

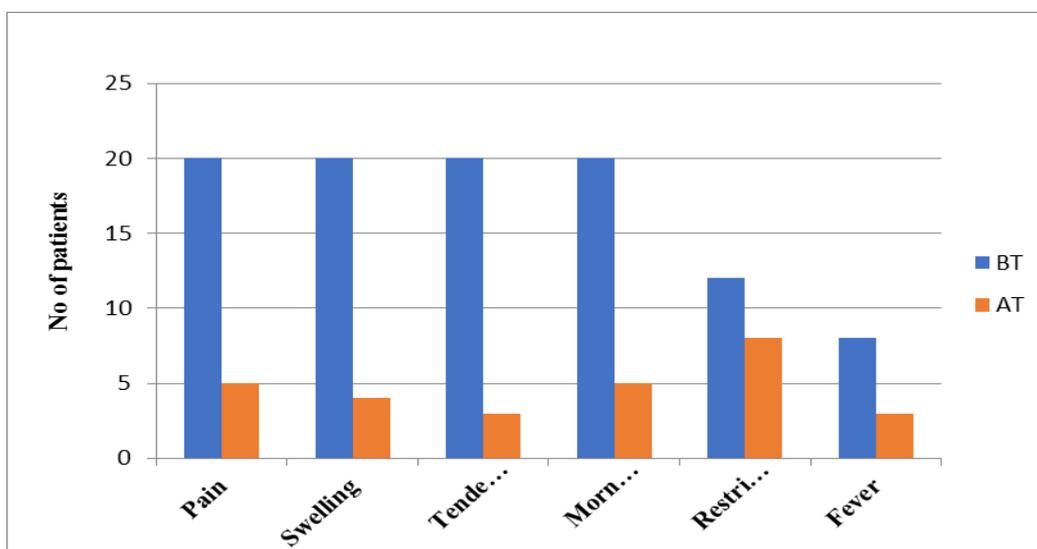


Chart 4: Case history chart of VAKV patients before and after treatment.

Table 1: Final outcome of VAKV patients before and after treatment.

Outcome measures	No. of Patients	B.T (Mean±SD)	A.T (Mean±SD)	P value
DAS	20	5.79± 0.73	4.31 ±0.53	p<0.05

CONCLUSION

The results of this pilot study suggest that this combination of *Siddha* formulation is effective and safe in the treatment and management of *Vali Azhal Keel Vayu* (Rheumatoid arthritis).

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