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Combined Efficacy Of Amirtharasa Mathirai And Suronitha Vatha Ennai In The Management Of Uthiravatha Suronitham - A Open Clinical Trial

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Abstract

Rheumatoid Arthritis (RA) is the most common persistent inflammatory arthritis, occurring throughout the world and in all ethnic groups. In India, the prevalence of this disease is affecting 0.75% of population. In Siddha system, Saint Yugimuni says that Vatha diseases alone are classified into 80 types. In which "Uthira vadha Suronitham" is one among them and the signs and symptoms of this disease can be correlated with Rheumatoid Arthritis (RA) in Modern science. The siddha formulation, "Amirtharasa Maathirai" is selected as Internal Medicine and Suronitha Vatha Ennai for External Medicine.The clinical trial was conducted with sample size of 40 patients. The patients are grouped into two. Totally 40 patients were selected, among this 20 treated at OP level and 20 in IP level. The pain assessment was done by the universal pain assessment scale before and after intervention. Observation made during the clinical study showed that the trial drug was clinically effective. Out of the 40 cases 28 cases showed good improvement, 6 cases had moderate improvement. The results are the mean pain score before treatment was 6.78 and after treatment it was reduced to 2.33. From this clinical trial it could be inferred that Amirtharasa mathirai and Suronitha vatha ennai possess good therapeutic efficacy in Uthiravatha suronitham.

Keywords: Uthiravatha suronitham, Rheumatoid Arthritis Amirtharasa mathirai, Suronitha vatha ennai, pain scale, Varmam therapy good improvement.

Introduction

Rheumatoid Arthritis (RA) is the most common persistent inflammatory arthritis, occurring throughout the world and in all ethnic groups. The clinical course is prolonged, with intermittent exacerbations and remissions. In India, the prevalence of this disease is affecting 0.75% of population [1]. Projected to the whole population, this would give a total of about seven million patients. In Siddha system of medicine the diseases are classified into three major categories that are Vatham, Pitham, and Kabam diseases. Siddha system is broadly classified into 4448 diseases which Saint Yugimuni says to Vatha diseases are 80 in number. In which "Uthiravadha Suronitham" is one among them [2, 3]. In Siddha system of medicine many formulations have been indicated for challenging and chronic diseases like Cancer, Brain tumours, Blood cancer, Cardiac diseases, Rheumatoid Arthritis, Oesteo Arthritis[4]. Around 40% of RA patients are registered

disabled within 3 years; around 80% are moderately to severely disable within 20 years and 25% will require a large joint replacement[5]. Many siddha formulations are available to treat Uthira vatha suronitham from Siddha system. So, Author chosen this siddha preparation after elaborated search and it is aimed to reducing not only the pain but also the restricted movements and other symptoms of this disease Uthira vatha suronitham. The drug **"Amirtharasa Maathirai"** chose as Internal Medicine and Suronitha Vatha Ennai as External Medicine.

Aim and objective

Primary Objective

To Evaluate the Safety and Therapeutic efficacy of "Amirtharasa Mathirai" (Internal) and "Suronitha Vatha Ennai" (External) in reducing the pain and restricted joint movements in the treatment of "Uthiravatha Suronitham (Rheumatoid Arthritis)

Secondary objective

To find out whether there are any side effects/ adverse effects produced by the trial drug Amirtharasa Mathirai (Internal) and Suronitha Vatha Ennai" (External) during treatment.

Materials and Methods

The Study on Uthiravatha Suronitham was carried out in the OPD and IPD of the Sirappu Maruthuvam, National Instiute of Siddha.

Medicine reference

Amirtharasa Mathirai (Internal) - Agasthiyar Mani 4000 Ennum Vaithiya Chinthamani Venbaa 4000 [6] . Suronitha Vatha Ennai (External) - Theraiyar Vaagadam [7]

Study Design

A Pilot clinical trial

Study Period

48 Days

Follow-up -2 months

Sample Size

Total 40 patients (20 OP + 20 IP).

Out-Patients were asked to visit the hospital once in 7 days. For Out-Patients the drugs were given for 48 days and the clinical assessment was done on 0^{th} day, 8^{th} day, 15^{th} day, 22^{th} day , 29^{th} day, 36^{th} day, 43^{th} day and 49^{th} day.

Treatment

Internal medicine

Amirtharasa Mathirai – 1 (130 mgs) - twice a day

External medicine

Suronitha vatha Ennai.

Inclusion Criteria

- Age: 20 - 60 years.
- Sex: Both male and female.
- Symmetrical joint involvement.
- Arthritis of three or more joints.
- Rheumatoid factor positive or negative.
- Morning stiffness.
- Deformities like Swan neck deformity and Button hole deformity.
- Swelling especially in the inter - phalangeal joint.
- Patients willing for admission and stay in IPD or willing to attend OPD.
- Patient willing to undergo Radiological investigation and for laboratory investigation.
- Patient willing to sign the informed consent stating that he/she was consciously stick to the treatment during 48 days but could OPD out of the trial of his/her own conscious discretion.

Exclusion Criteria

- Drug addicts
- Pregnancy and lactation
- Tubercular arthritis
- Any other serious systemic illness

- Osteoarthritis
- Psoriatic arthritis
- Gouty arthritis
- HIV & AIDS

Withdrawal Criteria

- Intolerance to the drug and development of adverse reactions during drug trial.
- Poor patient compliance and defaulters.
- Patient turning unwilling to continue in the course of clinical trial.

Outcome Assessment

- Assessment of pain was made by Universal pain assessment scale. Other clinical signs and symptoms were assessed by Gradation method.
- Laboratory investigations were made at the end of the study.

Grade 0 : No Pain
Grade 1 -3: Mild pain
Grade 4-6 : Moderate pain
Grade 7-10: Severe pain

- *Ref: Clinical Manual for Nursing Practise.(National Institute of Health Warren Grant Magnuson Clinical Center)*

Restricted movements is assessed by the following Gradation,

- Grade 1 – Able to perform normal duties
- Grade II – Moderate Restriction – Self care is possible
- Grade III – Marked restriction – Limited self care/some assistance required.
- Grade IV – Confined to bed or wheel chair

Results and discussion

The clinical trial of Amirtharasa Mathirai and Suronithavatha Ennai was given for 48 days with diet restriction. Before and after treatment the assessment was made and is list below.

Table No: 1. Reduction of pain

Pain	Before Treatment		After Treatment	
	No of patient	Percentage %	No of patient	Perce-ntage
Severe Pain	27	67.5%	3	7.5%
Moderate Pain	11	27.5%	4	10%
Mild Pain	2	5%	24	60%
No Pain	-	-	9	22.5%
Total	40	100%	40	100%

Observation

In this study, before treatment 67.5% of cases had Severe pain, 27.5% of cases had Moderate pain and 5% of cases had Mild pain.

After treatment 7.5% of cases had severe pain, 10% of cases had Moderate pain, 60% of cases had Mild pain and 22.5%of cases had No pain.

Table No: 2. Functional ability gradation

Grade	No. of patients			
	Before Treatment	%	After Treatment	%
Grade IV	-	-	-	-
Grade III	18	45%	3	7.5%
Grade II	20	50%	9	22.5%
GradeI	2	5%	28	70%

Total	40	100%	40	100%

After the treatment among 40 cases, Restriction was reduced in 70% of cases, Mild restriction was found in 22.5% of cases, and Moderate restriction was found in 7.5% of cases.

Table No: 3. Overall result after treatment

Improvement	No of cases	Percentage %
Good improvement	28	70%
Moderate improvement	6	15%
Mild improvement	3	7.5%
No improvement	3	7.5%
Total	40	100%

In this trial, 70% cases showed Good improvement, 15% cases showed Moderate improvement, 7.5% cases showed Mild improvement and 7.5% cases showed No improvement.

Statistical analysis

Treatment with the Trial Drug

SPSS software was used to perform statistical analysis. Basic descriptive statistics include frequency distributions and cross-tabulations were performed. The quantity variables were expressed as Mean ± Standard Deviation and qualitative data as percentage. A probability value of <0.05 was considered to indicate as statistical significance. Paired‘t’ test was performed for determining the significance between before and after treatment.

Table No: 4. Paired Samples Statistics

	Mean	N	Std. Deviation	Std. Error Mean
BEFORE	6.78	40	1.790	0.283
AFTER	2.33	40	2.005	0.317

The mean± standard deviation of pain score at before and after treatment were 6.78 ± 1.79 and 2.33 ± 2 respectively which is statistically significant (t= 13.02 p<0.001).

The pain assessment was done in all the 40 patients participated in the trial. The mean pain score before treatment is 6.78 after treatment it is reduced to 2.33**.** Hence this study reveals Varmam treatment along with trial medicines is to be very effective in the treatment of Uthiravatha Suronitham.

Conclusion

The study shows that about 82.5% of reported patients were women and after treatment most of the patients were comfortable and returned to their daily activity independent of others. Hence if the pain gets reduced in those individuals helping them to do their own daily routine by themselves is itself a big relief for those people. Hence the study concludes that, the trial drugs are clinically effective in reducing the pain, swelling and restricted movement in Uthiravatha Suronitham patients. However further work with large number of patients should be carried out towards finding the ideal dose response.

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