ORIGINAL ARTICLE

The efficacy of *Ayurvedic* treatment for rheumatoid arthritis: Cross-sectional experiential profile of a longitudinal study

Krishna Kumar P. R.

BAMS, Ayurvedic Trust, Trichy Road, Ramanathapuram, Coimbatore, Tamil Nadu, India

ABSTRACT

Context: Allopathic and Ayurvedic physicians collaborated on a study of traditional medicine, which was sponsored by the World Health Organization. **Aims:** The aim of the study was to test the efficacy and safety of Ayurvedic treatment for rheumatoid arthritis (RA). **Settings and Design:** This study was conducted at the Ayurvedic Trust, Coimbatore, India. **Materials and Methods:** In this unique study of classical Ayurvedic treatment for RA, allopathic physicians enrolled a total of 290 patients with a confirmed diagnosis of RA over a 7-year period, and once every 6 weeks evaluated Ayurvedic treatment outcomes on the basis of American Rheumatism Association criteria: grip strength, walking time, number of swollen and painful joints, joint count, functional class, erythrocyte sedimentation rate, and rheumatoid factor. Ayurvedic physicians administered individualized treatment, closely adhering to principles set forth in classical Ayurvedic texts. The duration of treatment varied from 1 to 6 months. **Statistical Analysis Used:** Due to limitations in computer technology in the 1970s, the data were not computerized. Therefore, data for 12 months at a time were analyzed, using repeated measures t-test. Measures of central tendency (means) and probability values were reported. Results from the patients enrolled and discharged at the end of the first year of the study (N = 33) are presented in this paper. **Results:** There was statistically significant improvement in all parameters from admission to discharge. **Conclusions:** The results indicated that classical Ayurvedic treatment was effective in this first cohort of patients who completed treatment. Even patients with severe functional limitations showed significant improvement. Although there was no control group, the results are positive enough to warrant further study of classical Ayurvedic treatment for RA in controlled trials.

Key words: Ayurveda, longitudinal study, rheumatoid arthritis

INTRODUCTION

Ayurveda has been recognized by the World Health Organization (WHO) as a complete system of natural medicine, but it is not widely known that the first-ever study of a traditional medical system sponsored by WHO was of complete, classical *Ayurvedic* treatment for rheumatoid arthritis (RA), conducted in collaboration with the Indian Council for Medical Research (ICMR) and the *Ayurvedic* Trust, Coimbatore, Tamil Nadu, India, from 1977 to 1984.[1] This unblinded, longitudinal study entitled, "The WHO/ICMR Study of the Efficacy of *Ayurvedic* Treatment for Rheumatoid Arthritis," enrolled 290 patients with RA over a 7-year period, and was conducted at the *Ayurvedic* Trust in Coimbatore, India.

This study is unique in at least two ways: (1) in an unprecedented move, the *Ayurvedic* Trust opened up their treatment methods to the scrutiny of allopathic physicians and allowed them to formally evaluate Ayurveda according to rigorous allopathic criteria; and (2) It was the first time that both *Ayurvedic* and allopathic physicians collaborated on a study of *Ayurvedic* medicine, in which the *Ayurvedic* physicians exclusively provided the treatment. Statistical analysis was performed by

Address for correspondence:
Dr. Pankajam Ramavarier Krishna Kumar,
Arya Vaidya Chikitsalayam and Research Institute,
PO Box No. 7102, Trichy Road, Ramanathapuram,
Coimbatore – 641 045, Tamil Nadu, India.
E-mail: mdoffice@avpayurveda.com

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an expert medical statistician. Each patient was evaluated at several different time points using the American Rheumatism Association (ARA) criteria,[2] thus yielding baseline controlled longitudinal repeated measures data. Unpublished reports of the allopathic experts' assessments and statistical analysis together indicate that, in this study, *Ayurvedic* treatment for RA was safe and effective, and provided symptomatic relief without harmful side effects.

There are no published studies that have tested Ayurveda as a whole system or its multiple modalities for the same disease at the same time.[3] Although there have been several studies of *Ayurvedic* treatment for various conditions, including RA,[4-6] they do not constitute true tests of classical Ayurveda because they did not allow for individualization of therapy, nor did they follow classical texts of Ayurveda for the treatment of RA.[7] Although three decades have passed since its inception, this study of classical *Ayurvedic* treatment for RA still remains the only one of its kind.

While allopathic treatment of RA is improving, remission remains rare and treatment remains unsatisfactory.[8] Therefore, a search for effective alternative and additional therapies for this disease continues. There is a growing interest in this study[9] and importantly, it was the inspiration for a recently completed double-blind, placebo-controlled, randomized pilot clinical trial, sponsored by the National Institutes of Health, USA, of classical *Ayurvedic* outpatient treatment for RA.[10]

The data archive housed at the *Ayurvedic* Trust contains descriptive analyses for every 12 months of the study for preparing the annual reports. In this paper, we present the outcomes for the first cohort of patients who completed their treatment during the first year of the study (1977–1978).

Materials And Methods

The ICMR team was responsible for the study design, confirmation of RA diagnosis, and enrollment of patients, and for the evaluation of the efficacy of *Ayurvedic* treatment, based on ARA criteria.[2] The *Ayurvedic* physicians administered the treatment, closely adhering to the principles set forth in classical *Ayurvedic* texts.[11] There was no control group.

Potential participants for the study were drawn from the outpatient department of the *Ayurvedic* Trust hospital and selected on the basis of *Ayurvedic* criteria for *vatarakta* by the *Ayurvedic* panel consisting of three *Ayurvedic* physicians. Participants who had diseases and conditions which would likely delay or alter the *Ayurvedic* treatment plan for *vatarakta* were excluded. The exclusion criteria jointly decided by the *Ayurvedic* and allopathic investigators were: Jaundice, diabetes, dysentery, pleurisy, tuberculosis, cardiovascular disease, leprosy, syphilis, ulcerative colitis, severe arthritis, iritis, asthma, epilepsy, mental illness, Parkinson's disease, herpes, neuropathy, and chronic urinary infection.

The selected patients who were all confirmed as having *vatarakta* were then sent to the allopathic panel consisting of four physicians, who evaluated them for RA on the basis of histological, serological, biochemical, and radiological tests. Only those with a confirmed diagnosis of RA, as determined by the allopathic panel, were admitted to the study as inpatients to undergo *Ayurvedic* treatment and periodic evaluations by both allopathic and *Ayurvedic* physicians. Of the patients referred by the *Ayurvedic* physician, the allopathic panel confirmed approximately 66% as having RA.

Since this was a study of classical *Ayurvedic* treatment, the *Ayurvedic* physicians were free to prescribe any combination of medicines and therapies based on their clinical judgment. Thus, the patients received individualized therapy as per principles specified in the *Ayurvedic* classical texts. Treatment included several pharmacological dosage forms of internal herbal medicines (*kashayams, arishtams, gulikas, lehyam,* and *choornam*), specialized oil therapies (*sneha-sweda*), purificatory therapies (*panchakarma chikitsa*) including medicated enema (*vasti*, or *basti*, as it is commonly known) and therapeutic purgation (*virechana*), external application of analgesic herbal pastes (*lepa*), medicated oils (*oushadha siddha taila*), and dietary and lifestyle modification. Patients were in treatment until they were considered well enough for discharge, which varied between 1 and 6 months after admission.

The evaluation of the efficacy of *Ayurvedic* treatment was done once every 6 weeks exclusively by the allopathic panel, on the basis of criteria established by the ARA once every 6 weeks.

Outcome measures (ARA Criteria)

The following were assessed at admission, once every 6 weeks during treatment, and at discharge: grip strength (mm of mercury), number of painful joints, number of swollen joints, walking time (25 and 50 ft, s), joints with active RA, joint count, functional status, erythrocyte sedimentation rate (ESR) at 0.5 and 1 h, and rheumatoid factor (RF).

Safety assessments

Also once every 6 weeks, the following tests were done: liver function tests such as SGOT, SGPT, serum protein, serum bilirubin, serum alkaline phosphatase, and prothrombin index; renal function tests including blood urea and serum creatinine; and complete blood count measures including white blood count, lymphocytes, PCV%, and hemoglobin.

Analyses

Data were recorded by both the allopathic and *Ayurvedic*

physicians in separate records for each patient. Outcome and efficacy endpoints were extracted for analysis by the medical statistician.

Results

Results are presented for the first cohort of patients who were discharged at the end of the first year of the study. The *Ayurvedic* physicians screened and diagnosed 100 patients as having *vatarakta*. These prospective patients underwent preliminary screening by an allopathic physician and 80 out of the 100 were provisionally diagnosed as having RA. Nine out of 80 failed to report to the allopathic hospital for the confirmation of diagnosis. The allopathic panel confirmed an RA diagnosis in 66 of these remaining 71 patients. Two of these were not willing to undergo inpatient treatment, leaving 64 patients to be admitted to the study. Since patients were recruited on an ongoing basis, not all of them completed the study at the same time. At the end of the first year, results for 33 patients were available for statistical analysis.

Characteristics of patients at admission

There were more females (61%) than males. About 75% of the patients were in the age range of 15–44 years, and approximately 60% were classified as being in functional class III (limited only to little or none of the duties of usual occupation or self-care) and functional class IV (incapacitated, largely or wholly; bedridden or confined to a wheelchair; little or no self-care). Approximately, 25% of patients had had RA for more than 5 years, 50% for 1–4 years, and the rest for less than 1 year [Table 1]. The length of treatment varied from 1 to 6 months.

Table 1: Demographic and background characteristics at admission (*N* = 33)

Characteristics	*N*	Percentage
Male	13	39
Female	20	61
Age (years)		
Less than 15	2	6
15–24	8	24
25–34	10	30
35–44	7	21
45 or more	6	18
Functional class		
I	7	21
II	7	21
III	16	48
IV	3	9
Disease duration (months)		
Less than 6	6	18
6–11	3	9
12–23	6	18
24–35	3	9
36–59	6	18
60 or more	9	27

Efficacy outcomes

The outcome measures for assessing the change between admission and discharge included grip strength, walking time (50 feet and 25 ft), number of swollen and painful joints, joint count, ESR, and RF. Table 2 shows the change in parameters from admission to discharge as well as the scoring system used to calculate the joint count.

Grip strength

Grip strength was measured by a sphygmodynamometer inflated to 30 mmHg. A mean of six readings, three for each hand measured alternatively was taken. The mean grip strength of both hands was less than 150 mmHg in 91% of patients at the time of admission. At discharge, this proportion decreased to 73%. The mean grip strength for all 33 patients was 82 mmHg at admission and 111 mmHg at discharge, a statistically significant increase ($P < 0.001$).

Walking time

Walking time is measured as the time in minutes and seconds taken to walk a distance of 25 ft and 50 ft. At admission, 12% of the patients took 15 s or more to walk a distance of 25 ft and 12% could not walk at all. At the time of discharge, however, all the patients could walk, and 94% were able to walk a distance of 25 ft in less than 10 s. The mean walking time for 25 ft was 7.4 s at admission and 4.8 s at discharge, a statistically significant decrease ($P < 0.001$).

Swollen joints

The proportion of patients with at least 10 swollen joints was 27% on admission, but was only 6% at discharge. The mean number of swollen joints was 6.6 initially and 4.3 at discharge, a significant reduction ($P < 0.001$).

Painful joints

Whereas 33% of the patients had at least 10 painful joints initially, the figure was only 6% at discharge. In terms of mean values,

Table 2: Mean values of the change from admission to discharge (*N* = 33)

Parameter	Admission	Discharge	*t*	*P*-value
Mean grip strength of both hands (mmHg)	82	111	4.3	<0.001
Walking time for 25 ft (s)	7.4	4.8	4.9	<0.001
Walking time for 50 ft (s)	14.3	9.4	4.6	<0.001
Swollen joints	6.6	4.3	5.3	<0.001
Painful joints	7.8	3.6	8.8	<0.001
Joint count*	74	30	6.4	<0.001
ESR (0.5 h)	30	17	3.2	<0.01
ESR (1 h)	59	37	3.2	<0.01

*The following scoring system for the joint count was employed, and the final score was the sum of the scores for the left and the right side:
Temporomandibular, 2; Acromioclavicular, 1; Sternoclavicular, 4; Shoulder, 12; Elbow, 12; Wrist, 4; Carpus, 4; Hip, 24; Knee, 24; Ankle, 8; Astragulus, 4; Choparts, 4; Tarsal, 8.

the number of painful joints decreased from a mean of 7.8 at admission to 3.6 at discharge ($P < 0.001$).

Joint count

A joint count of 75 or more was observed in 52% of the patients initially, compared with only 18% at discharge. Conversely, no patient had a joint count of 0 to begin with, but a third of the patients did so at discharge. The mean joint count decreased from 74 to 30, which is statistically significant ($P < 0.001$).

Erythrocyte sedimentation rate

Considering the findings at 1 h, 48% of the patients had an ESR of 50 mm or more initially, compared with 27% at the time of discharge; the means were 59 and 37, respectively ($P < 0.01$). Findings at 0.5 h showed the same pattern, with a statistically significant reduction in the mean from 30 mm to 17 mm ($P < 0.01$).

Functional class

Whereas 19 (58%) of the 33 patients were classified as belonging to functional class III or IV at the time of admission, only 4 were classified as such at the time of discharge [Table 3]. In all, there were 16 patients (48%) for whom no change in the functional class occurred, including 7 classified as functional class I. An improvement by one class was observed in 11 patients (33%), by two classes in 2 (12%), and by three classes in 2 (6%). The overall improvement in the group was highly significant ($P < 0.001$).

Table 3: Functional class at admission and discharge (N = 33)

Functional class*	Admission *N* (%)	Discharge *N* (%)
I	7 (21)	14 (42)
II	7 (21)	15 (45)
III	16 (48)	4 (12)
IV	3 (9)	0

*Functional class: class I = complete ability to carry out all usual activities without handicaps; class II = adequate for normal activities despite handicap of discomfort or limited motion at one or more joints; class III = limited only to little or none of the duties of usual occupation or self-care; class IV = incapacitated, largely, or wholly. Bedridden or confined to a wheelchair; little or no self-care (American College of Rheumatology).

The influence of various background and pre-treatment factors (such as sex, age, disease duration, and functional class) was examined. In general, the improvement in males was better than in females [Table 4]. In the case of grip strength, walking time, and joint count, the contrasts were appreciable and statistically significant. Age did not have an impact on progress (results not shown). There was some evidence that patients who were in functional classes III and IV improved more than those in functional classes I and II, especially with respect to grip strength, walking time, and joint count [Table 5]. Although none of the differences was statistically significant, they were all in the direction of improvement.

There was clear evidence that patients with a short history of RA (less than 1 year) improved more than those with longer histories [Table 6]. The differences were highly significant in the case of grip strength, walking time, and joint count.

Rheumatoid factor

Only 3 (9%) patients never had a positive finding and 22 patients (67%) had a titer of 1/80 or more, including 5 (15%) with a titer of 1/640 or 1/1280. The RF was determined on admission and discharge in only 15 (45%) of the 33 patients. In 12 patients, there were at least two doubling dilution steps. Two patients showed no change and one had a rise in titer from 1/20 to 1/80. The improvement in the group as whole (12 decreases compared to 1 increase) was statistically significant ($P < 0.01$).

Follow-up of patients was not done routinely for all patients during the first year of the study. Consequently, follow-up data were available for only 14 (42%) of patients 2-4 months after discharge (not shown). Except for grip strength, which showed a statistically significant increase (111 to 129, $P < 0.01$), all other parameters showed a very slight decline from discharge to follow-up, and bordered on statistical significance. Compared with mean values at admission, however, follow-up values indicated improvement.

Discussion

This first-ever study of traditional medicine sponsored by the

Table 4: Influence of gender on progress from admission to discharge (*N* = 33)

Characteristic	Gender	Mean at admission	Mean at discharge	Change	*P*-value*
Mean grip strength (mmHg)	Male	115	164	49	0.02
	Female	60	76	16	
Walking time for 50 ft (s)	Male	16.8	8.0	8.8	<0.01
	Female	13.0	10.6	2.4	
Swollen joints	Male	5.6	3.2	2.4	>0.02
	Female	7.2	5.0	2.2	
Painful joints	Male	8.8	3.6	5.2	0.13
	Female	7.2	3.6	3.6	
Joint count	Male	95	31	64	0.02
	Female	61	30	31	
ESR (mm at 1 h)	Male	62	28	34	0.2
	Female	56	41	15	

*Probability value for the contrast between males and females is the change between admission and discharge assessments.

Table 5: Influence of functional class on progress (*N* = 33)

Parameter	Functional class*	Mean at admission	Mean at discharge	Change	*P*-value**
Mean grip strength (mmHg)	I and II	90	112	22	>0.2
	III and IV	76	110	34	
Walking time for 50 ft (s)	I and II	11.1	9.0	2.1	0.09
	III and IV	18.1	9.8	8.3	
Swollen joints	I and II	5.9	3.7	2.2	>0.02
	III and IV	7.1	4.8	2.3	
Painful joints	I and II	7.0	3.0	4.0	>0.02
	III and IV	8.5	4.1	4.4	
Joint count	I and II	61	23	38	>0.02
	III and IV	84	35	49	
ESR (mm at 1 h)	I and II	49	28	21	>0.2
	III and IV	65	41	24	

*Functional class: class I = complete ability to carry out all usual activities without handicaps; class II = adequate for normal activities despite handicap of discomfort or limited motion at one or more joints; class III = limited only to little or none of the duties of usual occupation or self-care; class IV = incapacitated, largely or wholly. Bedridden or confined to a wheelchair; little or no self-care (ACR), **Probability value for the contrast between functional classes I and II and functional classes III and IV is the change between admission and discharge assessments.

Table 6: Influence of disease duration on progress from admission to discharge (*N* = 33)

Characteristic	Disease duration	Mean at admission	Mean at discharge	Change	*P*-value*
Mean grip strength (mmHg)	<1 year	94	151	57	<0.01
	>1 year	77	94	17	
Walking time for 50 ft (s)	<1 year	14.7	7.7	7.0	0.01
	>1 year	14.1	10.4	3.7	
Swollen joints	<1 year	5.1	1.8	3.3	0.12
	>1 year	7.2	5.4	1.8	
Painful joints	<1 year	8.0	2.7	5.3	0.2
	>1 year	7.8	4.0	3.8	
Joint count	<1 year	83	16	67	0.02
	>1 year	71	37	34	
ESR (mm at 1 h)	<1 year	50	18	32	>0.20
	>1 year	63	44	19	

*Probability value for the contrast between the two groups is the change between admission and discharge assessments.

WHO and conducted almost three decades ago remains the only known study of complete classical *Ayurvedic* inpatient treatment for RA. This analysis of the first cohort of patients discharged from the study clearly indicates that they improved considerably as a result of *Ayurvedic* treatment. There was improvement (statistically significant) in the patients' condition from admission to discharge, according to all the ARA criteria used to evaluate the effectiveness of *Ayurvedic* treatment.

Women constituted approximately two-thirds of the sample. They were affected more severely by the disease and improved more slowly than men. Pretreatment factors such as disease duration and functional class showed interesting patterns of improvement. While overall improvement was greatest in those who were in the early stages of RA, even those who were in the more advanced stages (functional classes III and IV) showed significant improvement. Records indicate that in general, reduction in swelling was noted within a month, and 80% reported relief from pain in the first month after starting treatment. There was no evidence of liver, renal, or other toxicity due to *Ayurvedic* treatment.

Given the form of the data available in the archives, we have been limited to presenting the results of only a subset of patients in this paper. Other limitations related to the overall study design must be acknowledged and considered when interpreting the results of this study. First, there was no control group, which unfortunately limits the generalizability of this study. Second, patients taking steroids were also enrolled, and instead of having the drug gradually tapered and stopped as is medically recommended, the study protocol called for stopping the drugs abruptly upon admission. The resulting severe withdrawal symptoms delayed full *Ayurvedic* treatment in these patients (steroid group) by a few weeks. In this first cohort, steroid and nonsteroid patients were not compared with each other, but data were analyzed separately in subsequent cohorts for steroid and nonsteroid groups. Those analyses showed that the progress of the steroid group was slower than those who were not on steroids. The average length of treatment was 3 months for the nonsteroid group compared with 6 months for steroid group. Third, the admission criteria did not exclude children who would be considered as suffering from

juvenile RA, a disease entity treated differently from adult RA.

Despite the abovementioned limitations, it is a testament to the efficacy of *Ayurvedic* treatment for RA that the allopathic outcomes measured in this study were statistically significant and positive. It is reasonable to believe that classical Ayurveda, with its hallmark individualized, holistic treatment, was responsible for the improvement noted in this varied group of patients regardless of disease duration, functional status, and age.

An unexpected consequence of the study's methodology underscored Ayurveda's strength in diagnosing RA in the prodromal stages when symptoms are very subtle. Only two-thirds of those initially diagnosed by the *Ayurvedic* physicians were confirmed by the allopathic panel as having RA and included in the study. The *Ayurvedic* physicians independently and successfully treated the excluded individuals for *vatarakta*. As these patients were in the very early stages of the disease, they benefited greatly from the treatment, supporting the allopathic view that treating RA in its early stages yields better outcomes.

This study served to bring attention to Ayurveda, at a time when it was trying to transcend centuries of colonial neglect,[12] and even when judged by allopathic criteria, it showed that *Ayurvedic* treatment was successful in treating a complex, chronic disease like RA. Of equal or perhaps greater importance might be the fact that the *Ayurvedic* physicians documented treatment and outcomes (according to *Ayurvedic* criteria) meticulously and innovatively. They designed questionnaires based on *Ayurvedic* principles, defined variables according to *doshas* and stage of disease, and performed quantitative analysis of *Ayurvedic* outcome measures. The *Ayurvedic* physicians were also able to test their own theories in this way. For example, the expected degree of improvement based on Ayurveda's stage-wise classification and its prediction that patients of a certain constitution type (a *vata-pitta* combination) would be more prone to developing the disease were supported. The equivalence of the classical *Ayurvedic* diagnosis of *vatarakta*[11] and the allopathic diagnosis of RA as per ARA criteria[2] was also confirmed. Thus, this study provides credence to the observation that a multifaceted traditional medicine system can lend itself to quantitative and objective analysis.

Approximately 160 full sets of patient records (*Ayurvedic* and allopathic) are available in the study archives. There is a wealth of longitudinal data from clinical allopathic examinations, separate *Ayurvedic* evaluations, and self-evaluations of patients. The fact that *Ayurvedic* treatment was documented in such great detail makes it a valuable data source for learning more about classical *Ayurvedic* treatment for RA and for designing controlled studies in the future to reveal its full therapeutic potential.

A computerized database of this rich and unique data resource can help researchers generate and test hypotheses regarding the efficacy of *Ayurvedic* treatment in ways not envisioned by the original investigators, by taking advantage of advances in statistical software and methodology. Given the detailed documentation of *Ayurvedic* treatment, there is also great potential for qualitative analysis and serving as a valuable learning resource for students of Ayurveda.

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