Health-related quality of life in rheumatoid arthritis patients in South India

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ABSTRACT

Introduction: Assessment of health-related quality of life (HRQL) has been gaining much importance in the care of rheumatoid arthritis (RA). This study was aimed at assessing the HRQL of patients with RA in South India.

Methods: HRQL of consenting RA patients, on disease-modifying anti-rheumatoid drugs (DMARDs) and attending a rheumatology clinic, was assessed using a self-filled Malayalam version of the Functional Assessment of Chronic Illness Therapy-Fatigue (FACIT-F) version 4 questionnaire.

Results: 50 patients were assessed out of 58 responses. The mean duration of the disease was 7.29 years. 46 patients (79.3 percent) had tried complementary and alternative medicines (CAM). The HRQL score in patients who were put on DMARDs within six months of symptoms was significantly higher (p-value is equal to 0.008).

Conclusion: HRQL in patients treated early by DMARDs is significantly higher in this region, where a good proportion of patients seek the CAM for treatment of RA.

Keywords: complementary medicine, disease-modifying anti-rheumatic drugs, quality of life, rheumatoid arthritis,

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INTRODUCTION

Rheumatoid arthritis (RA) is a chronic, systemic, inflammatory, progressive disease occurring in about 0.75% of the adult population in India.[1] The physical damage caused by the illness can well be followed-up and curtailed. However, the psychological and social morbidities very easily evade the eyes of the clinician. Health-related quality of life (HRQL) questionnaires for patients are an answer to this issue.[2] HRQL is important for measuring the impact of the disease, and for evaluating the effects and cost-effectiveness of the treatment. There are not many studies from this region assessing the HRQL in patients with RA and its improvement with early treatment. This pilot study was undertaken to elucidate these concerns.

The Functional Assessment of Chronic Illness Therapy (FACIT) measurement system, under development since 1987, is a collection of HRQL questionnaires targeted to the management of chronic illnesses. It now includes over 400 questions, some of which have been translated into more than 45 languages. Chronic fatigue is often an accompanying component of RA. The FACIT-fatigue (F) questionnaire, designed to measure anaemia-related fatigue in cancer patients, was validated for RA patients by Cella et al.[3] The entire set of 40 questions is divided into five subsets – physical well-being (PWB), social well-being (SWB), emotional well-being (EWB), functional well-being (FWB) and additional concerns (fatigue subset). Each of these subsets consists of a few questions with five responses ranging from zero to four, depicting "not at all" to "very much". The validated translated version of FACIT-F in the regional language, Malayalam, was introduced in the year 2000, for a study in head and neck cancer patients. The ready availability of a simple questionnaire in the regional language, which has been validated for a chronic disease (head and neck cancer) in this region, prompted us to choose FACIT-F as the instrument for this study.

This pilot study was designed to assess the feasibility of using the Malayalam-translated FACIT-F questionnaire for determining the HRQL status of patients with RA and to study the treatment options adopted for RA by the community in this region. We also wanted to determine any statistically significant difference in the HRQL between patients who were initiated on disease-modifying anti-rheumatoid drugs (DMARDs) early in the course of the disease and those who were initiated later. Complementary and alternative medicine (CAM) has been popularised internationally, especially for rheumatic diseases, over the past many decades. Research has shown

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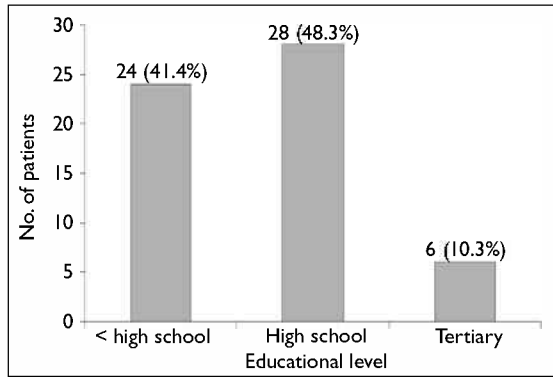Email: ashishjacob mathew@gmail.com

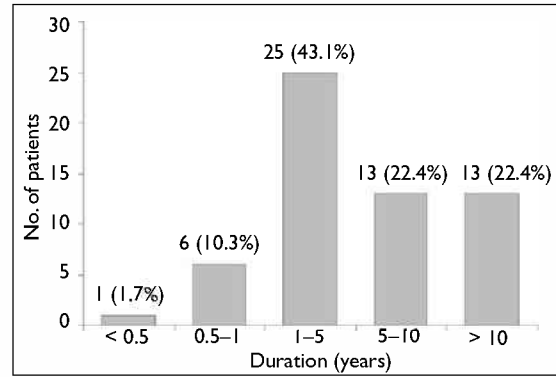**Fig. 1** Bar chart shows the education status of the patients.

Fig. 2 Bar chart shows the total duration of the illness.

that 60%–90% of persons with arthritis use CAM and the foremost reason given for its use was to overcome the pain.[4] Kerala, a state in South India, is well known for its Ayurveda treatment, which has been handed down over generations. The traditional belief in the Ayurveda treatment for musculoskeletal disorders is unshakable in this region. We wanted to study the proportion of RA patients who sought treatment with CAM before presenting to the rheumatology clinic, and to assess the HRQL of these patients.

METHODS

The inclusion criteria for the study were all patients who were diagnosed to have RA by the American Rheumatism Association 1987 revised criteria,[5] were on DMARDs (started at least on the second visit) for a minimum period of one month before presentation, had a 28-joint disease activity score (DAS28)[6] of 2.6–5.1, attended the rheumatology clinic of the Medical College Hospital, Kerala, India, from March to August 2007, and consented to participate in the study. Patients with other comorbid chronic illnesses like type 2 diabetes mellitus, systemic hypertension, chronic depression, other connective tissue disorders and those who could not complete the questionnaire by themselves were excluded from the study. Patients in remission and those with high disease activity were also excluded.

Demographical details such as age, educational level, marital status and family income of the selected patients were recorded. The details of the disease were noted, such as the duration of the illness, time taken from the appreciation of the first symptom to the point of presentation to the clinic, point in time during the course of the disease when DMARDs were started and details of alternative systems of medicine sought. Following a detailed musculoskeletal evaluation, the selected patients were requested to complete a Malayalam version of the FACIT-F (version 4) questionnaire by themselves and to
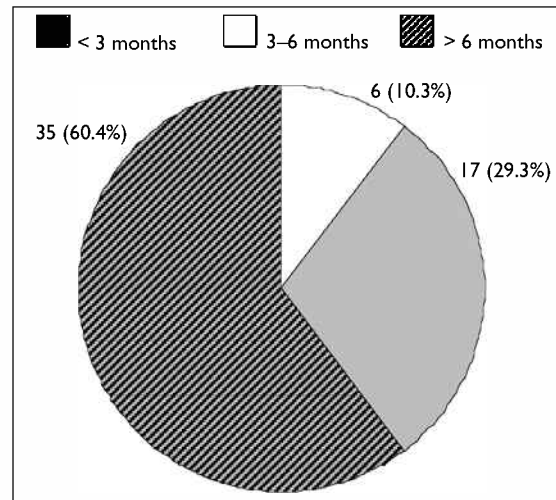

Fig. 3 Pie chart shows the duration of illness before presentation.

submit it on the same day. The responses were scored using the guidelines provided by the FACIT-CORE group.[7] Response scores to negatively-phrased questions were reversed and the scores were summed. Each subset was scored separately, and a high score represented a good quality of life. In cases where individual questions were skipped, scores were prorated using the average of the other answers in the scale. The total FACIT-G (general) score was obtained by summing individual subscale scores (PWB + EWB + SWB + FWB). The total FACIT-F score was obtained by adding the fatigue subset score to the FACIT-G score. The total score was considered appropriate for analysis if the overall item response rate was greater than 80%.

RESULTS

Of the 58 patients selected, only 50 (86.2%) completed at least 80% of the questionnaire. The mean age group of the 58 patients (ten males) was 43.14 years, and the mean duration of the disease was 7.29 years. All 58 patients had a moderate DAS28 of 3.2–5.1, assessed by three variables.

Table I. FACIT-G score results.

Demographic	Mean score	Median score	p-value
Gender			0.865
Male	51.95	50.17	
Female	51.96	52.00	
Total duration of disease			0.186
6–11 months	59.7	61.59	
1–5 years	50.39	50.33	
6–10 years	55.01	57.00	
> 10 years	44.14	45.00	
Pre-treatment symptom duration			0.008*
1–6 months	58.85	59.09	
> 6 months	48.05	47.75	

Maximum score of FACIT-G obtained as a sum of the individual subscale scores (PWB + EWB + SWB + FWB) is 108.
* p-value is significant.

Table II. FACIT-F score results.

Demographic	Mean score	Median score	p-value
Gender			0.53
Male	76.15	79.66	
Female	72.11	71.50	
Total duration of disease			0.189
6–11 months	87.36	88.50	
1–5 years	69.83	64.00	
6–10 years	75.86	71.00	
> 10 years	64.97	63.50	
Pre-treatment symptom duration			0.023*
1–6 months	81.35	86.00	
> 6 months	67.77	65.25	

Maximum score of FACIT-F obtained as a sum of the FACIT-G and fatique subset scores.
* p-value is significant.

There were 27 patients (46.6%) from the rural area and 31 (53.4%) from the urban area. Of the 58 patients, 46 (79.3%) had tried CAM before presenting to the clinic. Other demographical data and details of the illness are shown in Figs. 1–3. The mean and median scores from all the five subsets of the questionnaire were noted. In view of the small sample size, the median scores were analysed for their association with parameters in the demography and disease profile (Tables I & II). The scores were statistically analysed by non-parametric tests – Mann-Whitney U test and Kruskal-Wallis one-way analysis.

DISCUSSION

Although conducted in a small cohort of RA patients, this study was the first of its kind from this region. The main limitations of this pilot study were its relatively small sample size and the lack of a validated musculoskeletal-specific questionnaire in the regional language for assessing HRQL. A good proportion (86.2%) of the questionnaires distributed could be analysed, indicating a healthy acceptance of the Malayalam-translated FACIT-F questionnaire, although it is yet to be validated in RA patients. In recent years, assessing HRQL has become an integral part of RA care globally. It is cardinal that the questionnaire used for assessing HRQL should be regionally applicable and based on the practices of the population from that particular region. However, widely-used instruments, like the short form 36 (SF-36),[8] are designed mostly for the Western world. Thus, easy accessibility of an ideal HRQL instrument is always a notable problem.

Studies have shown that HRQL is dependent on disease activity to a great extent.[9] In order to minimise the selection bias, we decided to exclude the patients who were in the remission phase (DAS28 score < 2.6) and those with severe disease activity (DAS28 score > 5.1). All selected patients in the study had a moderate DAS28 of 3.2–5.1. The HRQL was significantly higher in patients who were started on DMARDs early in the course of the disease (within six months of initial symptoms). There was a significant difference in the FACIT-G scores (p = 0.008) and FACIT-F scores (p = 0.023) between the two groups. The treatment of RA has seen a paradigm shift in the last decade. More emphasis is being given on early detection and aggressive intervention in order to prevent disability and irreversible damage. The pace of radiographic erosion, which progresses very fast in the initial phase of the disease, can be retarded by effective control of the disease activity.[10] Studies have shown the benefit of early therapeutic intervention in RA.[11] However, studies on improvement of the HRQL with early treatment of RA are still lacking in this country. Although it is not statistically significant, the total duration of the disease also had an inverse relationship with the FACIT scores. A larger study population will give a clearer picture of these variables.

The firm belief of the population in CAM for the treatment of arthritis was an interesting observation in this study. A vast majority (79.3%) of the patients had tried CAM before presenting to the rheumatology clinic. Kerala is a state with a very high literacy rate and high standards of living, and where CAM has long been well recognised as the best cure for arthritis. Although the patients have direct access to the rheumatology clinic of the Medical College Hospital, most of them present themselves or are referred by physicians only after noticing joint deformities. Rheumatology as a specialty is still in its infancy and the medical training in undergraduate as well as postgraduate levels in this country is still grossly inadequate. Regular

continuing medical education for physicians also needs to be arranged to train them to detect patients with RA at the earliest possible moment and refer them to a specialist. Awareness among the population regarding improvement in the quality of life with early intervention needs to be emphasised. When health education programmes for chronic diseases like diabetes mellitus and hypertension are increasingly being implemented, the concerned authorities should also undertake to spread awareness about debilitating diseases like RA. A well-designed study in a large population will highlight this need to a large extent.

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