



Non Biological Dmards Therapy in Psoriatic Arthritis: A Prospective Clinical and Radiological Outcome Study

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Introduction

In patients with mild Psoriatic Arthritis (PsA) NSAIDs may be adequate for the relief of pain and inflammation but that do not alter the course of the disease. Non Biological DMARDs like Methotrexate (MTX), Sulfasalazine, Leflunomide and Cyclosporine when used alone or in combination help in limiting the disease progression. Choosing the best treatment in PsA has no thumb rule and response may vary from patients to patients. The drugs are employed in the more aggressive form of PsA with multiple joint involvement of axial skeleton with or without of appendicular skeleton. DMARDs work by blocking the inflammation caused by our human immune system. MTX is usually the first line drug, if this proves ineffective Leflunomide, Sulfasalazine and cyclosporine are added in the treatment regimen.

Aim

The aim of the present study is to establish the efficacy of using non biological DMARDs in the treatment of moderate to severe Polyarticular Psoriatic Arthritis (PsA). The aim of the study is also to establish whether non biological DMARDs

act alone or in combination therapy. It shall also be our aim to reduce the optimal period of time for which the therapy should be continued in order to achieve perceivable clinical improvement in terms of number of joints and the inflammatory activity and also to establish whether there is an improvement in radiological scores

Materials and Methods

Patient attending psoriatic arthritis clinic at Sree Balaji Medical College and Hospital, Department of Orthopedics from January 2012- January 2017 (5 years) and those who fulfill the inclusion criteria are enrolled in the study.

Inclusion criteria

- Both male and female patients were included in the study.
- Patients in the age group 25 to 55 years were included.
- Patients who had earlier been treated with steroids and Biologic DMARD's were excluded from the study.
- Patients with normal liver and renal function test alone were included.

Exclusion criteria

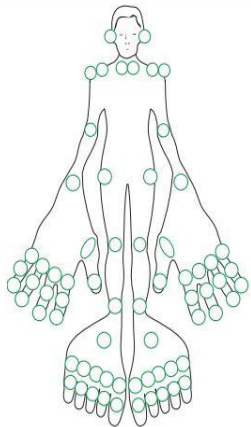
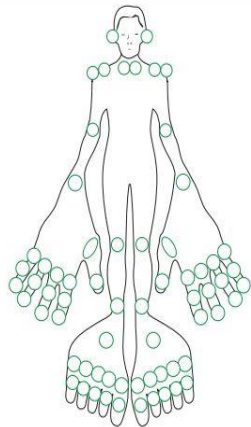
- Patients concomitantly using NSAIDs were excluded from the study.
- Patient not conforming to the above inclusion criteria were excluded from the study.

All patients were initially initiated with 12.5 mgs twice a week of Methotrexate (MTX) along with folic acid 20mg OD. Liver function tests were checked once in four weeks. Patients not showing improvement with MTX alone were augmented with Sulfasalazine, or a combination of Leflunomide (100 mg/day loading dose for 3 days followed by 20 mg/day orally) with sulfasalazine (sulfasalazine 2000 mg/day) or a stand-alone treatment with cyclosporine (cyclosporine 3 mg/kg/day). At the end of six months of treatment and thereafter once in six months until completion of 48 months course the response of the patient is assessed on the following criteria. Swollen and tender joint counts, joint/pain tenderness score, patient and physician global assessment, total Arthritis Impact Measurement Scale score and

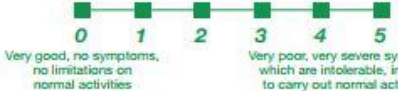
spondylitis functional index. Radiological scores were assessed at the start of the treatment and compared after every 12 months of treatment until completion of 48 months.

Joint Count Scoring Sheet

Tender and swollen measurements

 <p>Tender Joints: Number ____/68</p>	 <p>Swollen Joints: Number ____/66</p>
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Global VAS Pain ____/10

Global PsARC Assessment			
Patient and physician global assessment Recommended questions for the patient and physician using a 0–5-point Likert scale.		PsARC criteria (pre-treatment)	
Patient (PtGA) “Considering all the ways your arthritis affects you, how are you feeling today?” 		Tender (0-68) <input type="text"/> PtGA	Swollen (0-66) <input type="text"/> PGA
Physician (PGA) “Considering all the ways the arthritis affects your patient, how is your patient feeling today?”		Tender (0-68) <input type="text"/> PtGA	Swollen (0-66) <input type="text"/> PGA
		Definition of the criteria: Response = improvement in ≥ 2 of the 4 tests: <ul style="list-style-type: none"> • One of which must be the joint tenderness or swelling score • No worsening in any of the four measures • Improvement is defined as a decrease ≥ 30% in the swollen or tender joint score and a decrease ≥ 1 in either of the global assessments 	

Results

In this study 42% patients were female and 58% were male. Only 22% of the patients showed consistent improvement with MTX alone, of the remaining 78% of patients, 30% of patients were put on a combination therapy of MTX with

sulfasalazine, another 22% were put on leflunomide with sulfasalazine and the remaining 26% were put on stand-alone therapy with cyclosporine. At the end 12 months of therapy with regard to swollen and tender joint counts, joint/pain tenderness score, patient and physician

global assessment, total Arthritis Impact Measurement Scale score and spondylitis functional index, 42% of patients on MTX, 38% of patients with MTX with sulfasalazine, 34% patients with leflunomide and sulfasalazine and 55% patients with stand-alone cyclosporine therapy showed improvement. At the end of 48 months of therapy the cyclosporine stand-alone group performed the best with 78% of the patients improving, followed by 66% of the patients on MTX with sulfasalazine, 54% patients on MTX alone and 48% of the patients with leflunomide and sulfasalazine combination.

VANDER HEIJDE RADIOLOGICAL SCORES IN PsA

DRUG COMBINATIONS	START OF TREATMENT (SCORE OUT OF 528)	END OF TREATMENT (SCORE OUT OF 528)
MTX ALONE	342	144
MTX + SULFASALAZINE	376	126
LEFLUNOMIDE + SULFASALAZINE	359	210
CYCLOSPORINE ALONE	366	77

The Vander Heijde radiological score significantly improved in the cyclosporine alone group followed by the MTX + sulfasalazine group.

Discussion

The study establishes the utility of non-biological DMARDs in PsA patients. The response to various combinations are variable and the benefits in terms of clinical and radiological outcomes was best in the cyclosporine alone group. The MTX + Sulfasalazine and MTX alone group fared as the next best combination. The Leflunomide with sulfasalazine combination group fared as the least effective combination. This outcome compares well with the study done by Salvarani et al¹. The study by VADERELO et al² also came with similar conclusion.

Conclusion

Cyclosporine in the treatment of moderate to severe forms of PsA has established its efficacy both in clinical and radiological outcomes.

Reference

1. A comparison of cyclosporine, sulfasalazine, and symptomatic therapy in the treatment of psoriatic arthritis. Salvarani C¹, Macchioni P, Olivieri I, Marchesoni A, Cutolo M, Ferraccioli G, Cantini F, Salaffi F, Padula A, Lovino C, Dovigo L, Bordin G, Davoli C, Pasero G, Alberighi OD.
2. Recommendations for the management and treatment of psoriatic arthritis
3. Valderílio Feijó Azevedo, Rubens Bonfiglioli d, Roberto Ranzae, Célio Roberto Gonçalvesf, Mauro Keisermang, Eduardo de Souza Meirelles h, Marcelo de Medeiros Pinheiroi, Antonio Carlos Ximenesj, Wanderley Bernardo k, Percival DegraaSampaio-Barros.