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Original Research Article

A Study on Methotrexate Dosing Regimen for Plaque Type Psoriasis Patients

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Abstract:

Introduction: Methotrexate (MTX, a dihydrofolate reductase inhibitor), is a sys- temic treatment for psoriasis. (1–3) The effectiveness and safety of this drug are acknowledged in guidelines and studies from around the world.

Materials and Methods: This study was conducted in the department of Dermatology. Seventy three patients between 18 to 50 years of age sufferingfrom plaque type psoriasis with PASI score of >10 were included in the study after taking the informed consent. Oral methotrexate in a dose of 7.5 mg/week was given for 8 weeks.

Results*:* Out of 73 patients there were 45 (61.6%) males and 28 (38.4%) females. The mean ±SD age was 40.0±12.6 years. The mean baseline PASI score showed clear and comparable improvement from a mean ±SD PASI score of 14.8±4.2 to 4.9±4.3. Twenty nine (40%) patients had an almost complete remission duringthe 8 weeks of treatment.

Conclusion: Treatment with methotrexate for chronic plaque psoriasis brings satisfactory disease control and improved quality of life.

Keywords: Plaque psoriasis, Methotrexate, Efficacy.

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Introduction

Psoriasis is a complex inflammatory skin disease characterised by erythematous and scaly plaques. The disease requires early and continuous control similar to other chronic inflammatory disorders, such as rheumatoid arthritis and inflammatory bowel disease. In 2014, WHO recognised psoriasis as a serious non-communicable disease and, in a report from 2016, emphasised the lifelong nature of the disease and the need to urgently research and make accessible cost-effective medicines worldwide. [1] Development of monoclonal antibodies that target cytokines central to the psoriatic disease cascade, including tumour necrosis factor (TNF)α and interleukins 23 and 17A, has greatly broadened the therapeutic armamentarium; [2, 3, 4] however, survey findings indicate restricted use of these expensive treatments in fewer than 10% of patients with moderate to severe disease, even in high-income countries. [5] Methotrexate has been used in the treatment of psoriasis and psoriatic arthritis for more than 50 years, and is recommended as a first-line systemic drug for the treatment of moderate to severe psoriasis in US and European guidelines, [6] mainly on the basis of experience and health-economic considerations. However, in the absence of modern, well designed clinical trials, [7] uncertainties remain regarding the optimum dosing scheme, route of administration, and the safety profile, with appropriate monitoring in place. Only recently have high-quality data for methotrexate in psoriasis become available from three studies that tested the drug in comparison to the biological drugs adalimumab, [8] briakinumab, [9] and infliximab. [10] Although these studies differed in their dosing schemes, with methotrexate starting doses of 5 mg/week in conjunction with either a slower [8] or more rapid uptitration scheme, [9] and a starting dose of 15 mg/week in one study, [10] they all showed similar response rates to induction therapy according to a 75% reduction in Psoriasis Area and Severity Index score (PASI 75) in 36–42% of patients after 16–24 weeks of treatment. Long-term data showed a low stability of methotrexate response, with high dropout rates due to loss of efficacy in up to 70% of patients over 1 year. [9] The safety profile of methotrexate in these studies was similar with different dosing schemes in the first months of treatment, and generally similar to the profile of the biological drugs during longer-term treatment with regard to events perceived as of special concern with methotrexate, such as hepatopathy and leukopenia. Methotrexate was

given orally in all these studies, which might be a suboptimum route of administration in view of a trial in patients with rheumatoid arthritis that showed superiority of subcutaneous over oral methotrexate after 24 weeks. [11,12]

Materials and Methods

This study was conducted in the department of Dermatology. Seventy three patients between 18 to 50 years of age suffering from plaque type psoriasis with PASI score of >10 were included in the study after taking the informed consent. Oral methotrexate in a dose of 7.5 mg/week was given for 8 weeks. Patients between 18 to 50 years of age suffering from plaque type psoriasis of any duration with any severity of Psoriasis Area and Severity Index (PASI) score >10 were included in the study. Patients taking other treatments for the disease, suffering from anemia, thrombocytopenia, leukemia, active infection (e.g. tuberculosis, septicemia), peptic ulcer disease, renal or hepatic disease, cardiovascular disease and alcoholism were excluded. Pregnant women and lactating mothers were also excluded. Patients who were already taking treatment for psoriasis with Methotrexate or any other medicine were not included. Data was analyzed by using SPSS version 17 for descriptive statistics. The results were given in the form of frequency and percentage for qualitative data i.e. gender, site of involvement, efficacy. Mean and standard deviation for quantitative data i.e. age, severity of Plaque type psoriasis (measured by PASI score) and size of plaque.

Result

A total of eighty six patients between 18 to 50 years of age (Mean ± SD 40.0±12.6) with 45 (61.6%) males and 28 (38.4%) females suffering from plaque type psoriasis with PASI score of >10 were initially included in the study. Thirteen patients did not complete the 8-week treatment because of reversible elevations in liver enzyme levels (the highest level measured was an alanine aminotransferase level of 198 U per liter) and were excluded from the study. Majority of the patients had skin types IV or V. The predominant symptom was itching followed by joint pains. Sunlight with summer exacerbation was provocative factor in four patients, Koebner phenomenon was seen in three patients. No other precipitating factor was detected. The Psoriasis Area and Severity Index (PASI) was used to assess clinical status. Baseline and weekly PASI scores of all patients were maintained. The efficacy was labeled with a PASI score of < 5 at the end of 8 weeks. The mean baseline PASI score before treatment was 14.8±4.2 (Table-I). Patients were given oral methotrexate in a dose of 7.5 mg per week. The overall rate of response was high with 68 (93%) of 73 patients had reached the threshold for a minimal response - a 25 percent reduction from base line in scores after 8 weeks of treatment, before the dose was tapered. After 8 weeks, the primary outcome measure of disease activity (PASI score) showed clear and comparable improvement from a mean (SD) PASI score of 14.8±4.2 to 4.9.0±4.3 (Table-I). Twenty nine (40%) patients had an almost complete remission (defined as a reduction in the base-line score for the psoriasis area-and-severity index of more than 90 percent) during the 8 weeks of treatment. Partial remission (defined as a reduction in the base-line score of more than 75 percent) was achieved in 44 (60%) patients. The clearance time for psoriasis ranged from 5 - 7 weeks (mean 6±0.89 weeks).

Table 1: Efficacy of oral methotrexate on the study subjects.

Variable	Mean	Standard Deviation (SD)
Psoriasis Area and Severity Index (PASI) Baseline	14.8	4.2
At the end of 8 weeks	4.9	4.3
Clearance time for psoriasis (weeks)	6	0.89

Discussion

The present study demonstrated a good efficacy of oral methotrexate in the treatment of plaque psoriasis. Methotrexate and cyclosporine are often used in daily clinical practice, but which of the two is more effective has not been established.[14] Although we have not compared the two drugs in this study, results of this study showed that methotrexate can be used with good results. The current management of severe psoriasis is based on the principles of rotational therapy, which stresses frequent alternations in treatment approaches in order to reduce the cumulative risk of side effects.[13] The choice of treatment is influenced by short-term as well as long-term considerations, including the severity of the disease, the effectiveness of a given medication and its side effects, the patient's quality of life and the ease of treatment. According to the guidelines for the treatment of psoriasis, which are based on the 1997 review, UVB should be tried first, and if it proves to be ineffective, it should be followed in order by PUVA, methotrexate, acitretin, and finally, cyclosporine.[15,16] In latest consensus guidelines for the management of plaque psoriasis [17] published in 2012 it was proposed that methotrexate may be used as a first-line systemic drug for plaque psoriasis and compared with cyclosporine, has a more modest effect, but can be used continuously for years or decades. In a study done by Opmeer BC et al. [18], base line PASI score were 13.4 ± 3.6 and at the end of 16 week were 5.0± 4.5. In this study, mean baseline PASI score before treatment was 14.8±4.2 and at the end of 8 weeks of treatment was 4.9±4.3. The results are comparable with Opmeer study.

Despite the existence of guidelines [15,16], the regimens of both methotrexate vary substantially among countries in terms of the route (oral vs. intramuscular) and the dose. We used a starting dose of 7.5 mg of methotrexate per week. We chose this dose in the absence of evidence from dose-finding and treatment-duration studies. The guidelines, however, recommend an initial dose of 2.5 to 5 mg because of the risk of myelosuppression during the first 10 days of treatment.[13] The 8-week treatment period we used was proved to be effective in a previous study of methotrexate, in which more than 80 percent of the study population had clinical improvement.[19] Recently, multiple randomized control trials have been published about Secukinumab, a human anti- IL-17A IgG1κ monoclonal antibody, in patients with moderate-to-severe plaque psoriasis.20Their initial results are promising, however cost will remain a major factor for their widespread use.

Conclusion

Treatment with methotrexate for chronic plaque psoriasis brings satisfactory disease control, and improved quality of life. Further long term studies are needed to assess the safety of methotrexate.

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