Medac at the EADV 2017

Methotrexate for psoriasis: effective, safe, favourable

Medac with recent data on subcutaneous methotrexate from METOP study at the EADV in Geneva

Geneva / Wedel (September 15, 2017). Methotrexate (MTX) is the most frequently used conventional systemic drug in the treatment of psoriasis. With over 50 years of successful experience in this setting, it is no wonder that recent treatment recommendations consider MTX as first-line and cost-effective therapeutic for the systemic treatment of psoriasis.[1,2] And still the potential of MTX is often not fully exploited. In particular the dose and route of administration are aspects that should be considered.

At the Medac symposium[3] during the EADV 2017 Professor DENIS JULLIEN from Lyon recommended the subcutaneous (SC) route of administration and an initial starting dose of 15 mg MTX once weekly. JULLIEN pointed out that SC MTX is increasingly used with regard to benefits such as better bioavailability at higher doses and better gastrointestinal tolerance. Furthermore he underlined that the long-term data prove the safety and efficacy of Methotrexate. These are the reasons for MTX still being the first-line agent in psoriasis therapy. With reference to the substitution of folic acid he emphasized its' importance with regard to the reduction of the mucosal and gastrointestinal side-

1 Nast A et al. European S3-Guidelines on the systemic treatment of psoriasis vulgaris – Update 2015 – Short version – EDF in cooperation with EADV and IPC. J Eur Acad Dermatol Venereol 2015;29:2277-94.

2 Warren RB et al. British Association of Dermatologists' guidelines for the safe and effective prescribing of methotrexate for skin disease 2016. Br J Dermatol. 2016;175:23-44.

3 Medac satellite symposium „Safety and efficacy of subcutaneous methotrexate in psoriasis therapy – METOP study data" at the congress of the European Academy of Dermatology and Venereology (EADV), Geneva, 14 September 2017.

effects of methotrexate and the possible protective effect against hepatotoxicity.[4] JULLIEN mentioned that he uses 5 mg folic acid once weekly 24 hours after MTX.

The position of methotrexate as first-line agent in psoriasis therapy has currently been confirmed by the METOP trial results, published in The Lancet, beginning of this year. Professor Richard Warren from Manchester, being the first author, in his lecture presented the data of the Methotrexate Optimized treatment schedule in patients with Psoriasis (METOP) trial. This 52 week, randomised, double-blind, placebo-controlled phase 3 trial evaluated the efficacy and safety of self-administered subcutaneous methotrexate in patients with moderate to severe plaque-type psoriasis using an optimised dosing regimen.[5]

The results of the METOP trial showed a Dermatology Quality of Life Index (DLQI) ≤ 5 in 59 % of patients treated with MTX and a DLQI score of 0-1 in 43 % of patients, versus 34 % and 10 % in the placebo group at 16 weeks. The data demonstrate that subcutaneous methotrexate has a rapid onset of action and is significantly better than placebo in improving the skin condition and quality of life of plaque-type psoriasis patients with efficacy and safety sustained over one year. A subcutaneous injection of Metoject® 50 mg/ml[6] using a dose of 17.5 up to 22.5 mg/week greatly reduces the severity of plaque-type psoriasis – 45 % in the methotrexate group had a PASI 75 in week 52.

Furthermore skin biopsies demonstrated a correlation between the reduction in specific cytokines and inflammatory cells that suggests an inhibitory effect of methotrexate on the TH1/TH17 pathway in the skin. The sub-study showed that IL-17A mRNA levels dropped to 10 % and interferon γ mRNA levels decreased to 25 % compared to baseline. In parallel, the infiltrating CD3-positive T cells and CD11c-positive dendritic cells were reduced. In conclusion, WARREN and JULLIEN stated a favourable 52 weeks risk-benefit profile of SC MTX in patients with psoriasis.

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4 Shea B et al. Folic acid and folinic acid for reducing side effects in patients receiving methotrexate for rheumatoid arthritis. Cochrane Database Syst Rev. 2013;5:CD000951.

5 Warren RB et al. An intensified dosing schedule of subcutaneous methotrexate in patients with moderate to severe plaque-type psoriasis (METOP): a 52 week, multicentre, randomised, double-blind, placebo-controlled, phase 3 trial. Lancet. 2017;389:528-37.

6 Equivalent to Metoject®, Metex®, Trexject® and Rasuvo™.

With regard to the therapy costs of plaque-type psoriasis treatment, MARTIN O'LEARY from London presented a five-year sequencing cost model describing the superior cost-effectiveness of methotrexate therapy for moderate-to severe psoriasis. The analysis was conducted from a payer perspective in the UK and included costs relating to drug acquisition and administration, serious infections, and medical resource use. Subcutaneous methotrexate as first, second, or third line treatment in addition to oral MTX and CSA generated cost savings of £300–£311 million (£9,395–£9,728 per patient) over 5 years. Including SC MTX also delayed biologic treatment by 13.9 months. These British results are comparable to data from the United States: Methotrexate "had the lowest monthly costs per NNT to achieve PASI 75" [7].

Taking all these data and findings together, subcutaneous methotrexate is not only a well established important first-line systemic therapeutic for psoriasis but also safe, cost-effective and providing flexible dose adjustments if needed.

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[7] D'Souza LS, Payette MJ. Estimated cost efficacy of systemic treatments that are approved by the US Food and Drug Administration for the treatment of moderate to severe psoriasis. J Am Acad Dermatol. 2015;72:589-98.

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