

Clinical Audit on the Introduction of Apremilast into Ireland

Authors : F. O'Dowd, G. Murphy, M. Roche, E. Shudell, F. Keane, M. O'Kane

Abstract : Introduction: Apremilast (Otezla®) is an oral phosphodiesterase-4 (PDE4) inhibitor indicated for treatment of adult patients with moderate to severe plaque psoriasis who have contraindications to have failed or intolerant of standard systemic therapy and/or phototherapy; and adult patients with active psoriatic arthritis. Apremilast influences intracellular regulation of inflammatory mediators. Two randomized, placebo-controlled trials evaluating apremilast in 1426 patients with moderate to severe plaque psoriasis (ESTEEM 1 and 2) demonstrated that the commonest adverse reactions (AE's) leading to discontinuation were nausea (1.6%), diarrhoea (1.0%), and headaches (0.8%). The overall proportion of subjects discontinuing due to adverse reactions was 6.1%. At week 16 these trials demonstrated significant more apremilast-treated patients (33.1%) achieved the primary end point PASI-75 than placebo (5.3%). We began prescribing apremilast in July 2015. Aim: To evaluate efficacy and tolerability of apremilast in an Irish teaching hospital psoriasis population. Methods: A proforma documenting clinical evaluation parameters, prior treatment experience and AE's; was completed prospectively on all patients commenced on apremilast since July 2015 - July 2017. Data was collected at week 0,6,12,24,36 and week 52 with 20/71 patients having passed week 52. Efficacy was assessed using Psoriasis Area and Severity Index (PASI) and Dermatology Life Quality Index (DLQI). AE's documented included GI effects, infections, changes in weight and mood. Retrospective chart review and telephone review was utilised for missing data. Results: A total of 71 adult subjects (38 male, 33 female; age range 23-57), with moderate to severe psoriasis, were evaluated. Prior treatment: 37/71 (52%) were systemic/biologic/phototherapy naïve; 14/71 (20%) has prior phototherapy alone; 20/71 (28%) had previous systemic/biologic exposure; 12/71 (17%) had both psoriasis and psoriatic arthritis. PASI responses: mean baseline PASI was 10.1 and DLQI was 15. Week 6: N=71, n=15 (21%) achieved PASI 75. Week 12: N= 48, n=6 (13%) achieved a PASI 100%; n=16 (34.5%) achieved a PASI 75. Week 24: N=40, n=10 (25%) achieved a PASI 100; n=15 (37.5%) achieved a PASI 75. Week 52: N= 20, n=4 (20%) achieved a PASI 100; n= 16 (80%) achieved a PASI 75. (N= number of pts having passed the time point indicated, n= number of pts (out of N) achieving PASI or DLQI responses at that time). DLQI responses: week 24: N= 40, n=30 (75%) achieved a DLQI score of 0; n=5 (12.5%) achieved a DLQI score of 1; n=1 (2.5%) achieved a DLQI score of 10 (due to lack of efficacy). Adverse Events: The proportion of patients that discontinued treatment due to AE's was n=7 (9.8%). One patient experienced nausea alleviated by dose reduction; another developed significant dysgeusia for certain foods, both continued therapy. Two patients lost 2-3 kg. Conclusion: Initial Irish patient experience of Apremilast appears comparable to that observed in trials with good efficacy and tolerability.

Keywords : Apremilast, introduction, Ireland, clinical audit

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