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Long-term safety of etanercept in psoriasis: Retrospective study focused on infections

Diego Orsini, Alessandra Narcisi, Annalisa Arcese and Antonio Costanzo

Abstract

Objective: Retrospective study to evaluate the incidence of infectious adverse events in patients with psoriasis treated with etanercept.

Methods: Patients with psoriasis or psoriatic arthritis who were treated with etanercept (50 mg, administered weekly via subcutaneous injection) for ≥48 weeks were retrospectively enrolled. Patients were screened for occult infections before treatment commenced, and then every 12 months thereafter. Minor (not requiring hospitalization and/or discontinuation of treatment) and major (requiring hospitalization and/or discontinuation of treatment) infectious events were recorded.

Results: The study included 50 patients. Minor infectious events included self-limiting upper respiratory tract infections (six patients), lower urinary tract infections (one patient) and recurrent herpes simplex labialis (two patients). Major infections occurred in only two cases.

Conclusion: These data support the good safety profile of etanercept in patients with psoriasis or psoriatic arthritis.

Keywords

Etanercept, psoriasis, psoriatic arthritis, safety, tumour necrosis factor-α

Introduction

Psoriasis is a common immune-mediated skin disease that affects up to 3% of the population worldwide, and has an equal sex distribution.[1] LL37 is a psoriasis-associated T-cell autoantigen that has been considered the triggering factor for a T

Dermatology Unit, Department of Neurosciences, Mental Health and Sensory Organs (NESMOS), University of Rome "La Sapienza", Rome, Italy

Corresponding author:
Antonio Costanzo, Dermatology Unit, Department of Neurosciences, Mental Health and Sensory (NESMOS), University of Rome "La Sapienza", S. Andrea Hospital, via di Grottarossa, 1035, Rome 00189, Italy.
Email: antonio.costanzo@uniroma1.it

cell-mediated response.[2] This activates the immune response, resulting in inflammation and keratinocyte proliferation, thereby establishing a vicious circle in an autoamplification loop. Psoriatic arthritis is a hyperproliferative and inflammatory form of arthritis that is closely associated with psoriasis.[3] Numerous biological response modifiers have emerged in the treatment of psoriasis that have been engineered to target specific mediators of inflammation, such as tumour necrosis factor (TNF)-α, interleukin (IL)-17, IL-12 IL-23, and others.[4] The safety profile of biologics is higher than that of traditional immunosuppressive therapies.[5] Etanercept is a fusion protein that suppresses the activity of TNF-α,[6] a proinflammatory cytokine that is important in the human response to infections.[7] The aim of the present retrospective study was to evaluate the incidence of infective adverse events in patients with psoriasis treated with etanercept.

Patients and methods

Study population

The study retrospectively identified patients with psoriasis or psoriatic arthritis, treated with etanercept (50 mg per week, administered subcutaneously) for ≥48 weeks, between January 2007 and December 2013 at the Dermatology Unit, Department of Neurosciences, Mental Health and Sensory Organs (NESMOS), Sant'Andrea Hospital, University of Rome "La Sapienza", Rome, Italy. Inclusion criteria were: (i) aged ≥18 years; (ii) psoriasis area severity index (PASI) > 10 and/or psoriatic arthritis; (iii) QuantiFERON® TB Gold test negative (Quest Diagnostics™, Madison, NJ, USA); (iv) hepatitis B virus (HBV), hepatitis C virus (HCV) and HIV negative. Patients receiving concomitant disease-modifying antirheumatic drugs (D-MARDS) or steroid therapy were excluded.

The ethics committee of Sant'Andrea Hospital, University of Rome "La Sapienza", Rome, Italy approved the study, and all patients provided written informed consent prior to enrolment.

Data collection and study definitions

Data were extracted from medical records. Screening for HBV, HCV, HIV and tuberculosis was performed using standard methods before etanercept treatment and repeated every 12 months. Major and minor infectious events during treatment were recorded. Minor infectious events were defined as those that did not require hospitalization or discontinuation of etanercept therapy. Major infectious events required hospitalization and discontinuation of etanercept therapy.

Results

The study included 50 patients (34 male and 16 female; mean age 54.1 ± 14.30 years and 50.1 ± 16.26 years, respectively). All patients were followed-up for 48 weeks.

Minor infectious events included self-limiting upper respiratory tract infections (rhinitis, laryngo-tracheitis, otitis; six patients), one case of lower urinary tract infection and two of herpes simplex labialis recurrence (two patients). Major infections were observed in two patients (one case of *Streptococcus pneumoniae* pneumonitis and one case of peritonitis).

Discussion

Our data confirmed the good safety profile of etanercept in the treatment of patients with psoriasis. The relationship between biologic treatments and infectious disease in these patients remains unclear, however. The majority of studies have evaluated patients with rheumatoid arthritis or

inflammatory bowel disease, who have an increased relative risk of infections compared with those treated for psoriasis and psoriatic arthritis.[8] Rheumatoid arthritis itself is a risk factor for infectious disease, and these patients are frequently treated with concomitant immunosuppressive agents.[9] The safety profile of biologics may be associated with patient predisposition or disease-related factors, and not only to anti-TNF-α.

The present study is limited by the absence of a control group and the relatively small sample size. Further, larger scale studies are required to confirm the findings described.

In conclusion, we showed that etanercept therapy had a good safety profile in these patients with psoriasis. Etanercept and other biologic agents are characterized by a targeted mechanism of action interfering with specific molecules of the immune system. Thus, their safety profile is higher than that of traditional immunosuppressive therapies.

Declaration of conflicting interest

The authors declare that there are no conflicts of interest.

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References

1. Stern RS, Nijsten T, Feldman SR, et al. Psoriasis is common, carries a substantial burden even when not extensive, and is associated with widespread treatment dissatisfaction. *J Invest Dermatol Symp Proc* 2004; 9: 136–139.
2. Lande R, Botti E, Jandus C, et al. The antimicrobial peptide LL37 is a T-cell autoantigen in psoriasis. *Nat Commun* 2014; 5: 5621.
3. Nestle FO, Kaplan DH and Barker J. Psoriasis. *N Engl J Med* 2009; 361: 496–509.
4. Chiricozzi A. Pathogenic role of IL-17 in psoriasis and psoriatic arthritis. *Actas Dermosifiliogr* 2014; 105(Suppl 1): 9–20.
5. Nast A, Jacobs A, Rosumeck S, et al. Efficacy and Safety of Systemic Long-term Treatments for Moderate-to-Severe Psoriasis – A Systematic Review and Meta-Analysis. *J Invest Dermatol* 2015 Jun 5. doi: 10.1038/jid.2015.206.
6. Ducharme E and Weinberg JM. Etanercept. *Expert Opin Biol Ther* 2008; 8: 491–502.
7. Winthrop KL. Risk and prevention of tuberculosis and other serious opportunistic infections associated with the inhibition of tumor necrosis factor. *Nat Clin Pract Rheumatol* 2006; 2: 602–610.
8. Andersen NN and Jess T. Risk of infections associated with biological treatment in inflammatory bowel disease. *World J Gastroenterol* 2014; 20: 16014–16019.
9. Tan X, Balkrishnan R and Feldman SR. Infections associated with the use of tumor necrosis factor-α inhibitors in psoriasis. *J Drugs Dermatol* 2013; 12: e41–e45.