Influence of body mass index and weight on etanercept efficacy in patients with psoriasis: A retrospective study

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Abstract
Aim: To investigate the role of body mass index (BMI) and weight in the long-term efficacy of etanercept in patients with psoriasis.
Methods: Medical records were retrospectively analysed. Extracted data included weight, BMI, comorbidities and psoriasis area severity index (PASI). Patients were stratified by weight (<80 kg or ≥80 kg) and BMI (healthy, BMI 22 – 24.99 kg/m²; overweight, BMI 25 – 29.99 kg/m²; obese, BMI ≥30 kg/m²).
Results: The study included 66 patients. Body weight had no effect on etanercept efficacy. There was a significant reduction in etanercept efficacy in obese patients (n = 12) compared with healthy weight (n = 33) or overweight (n = 21) patients.
Conclusion: Obesity has a negative effect on the efficacy of etanercept in psoriasis.

Keywords
Anti-tumor necrosis factor-α, body mass index, body weight, etanercept, obesity, psoriasis

Introduction
The relationship between body mass index (BMI) and treatment with anti-tumour necrosis factor (TNF)-α agents (including etanercept) is unclear. Studies have found significant weight gain in patients with psoriasis treated with various anti-TNF-α therapies, but neither BMI nor weight gain were associated with clinical inefficacy.
Female, overweight or obese patients with axial spondyloarthritis have been found to have a lower response rate to anti-TNF-α drugs compared with male or healthy weight patients.⁴ We have shown that being female and having coexisting psoriatic arthritis were associated with increased risk of primary inefficacy to etanercept.⁵ The aim of the present study was to investigate the role of BMI and body weight in the long-term efficacy of etanercept in the treatment of psoriasis.

Patients and methods

Study population

This retrospective database analysis included consecutive patients with psoriasis referred to the Department of Dermatology, University of Rome Tor Vergata, Rome, Italy, between 30 January 2014 and 30 January 2015. Patients were required to have BMI > 22 kg/m² and to have undergone etanercept treatment for ≥ 4 years. A single investigator (A.G.) with no access to the patients analysed all data using anonymised database registries.

Patients were stratified according to body weight (<80 kg or ≥80 kg) and BMI (healthy, BMI 22 – 24.99 kg/m²; overweight, BMI 25 – 29.99 kg/m²; obese, BMI ≥ 30 kg/m²). Clinical efficacy was defined as a reduction in mean psoriasis area severity index (PASI) during treatment. Patients provided written informed consent prior to treatment. Ethical approval was not required due to the retrospective nature of the study.

Statistical analyses

Data were presented as mean ± SD or n of patients, and compared using last-observation-carried-forward (LOCF) analysis with Statistics software, version W1.59 (Blackwell Scientific Publications, Oxford, UK). A two-tailed P-value < 0.05 was considered statistically significant.

Results

The medical records of 300 consecutive patients were evaluated, 66 of whom fulfilled the inclusion criteria. The demographic and clinical characteristics of these 66 patients are shown in Table 1. There were no
statistically significant changes in body weight during etanercept treatment.

Table 2 shows data regarding psoriasis severity and comorbidities in patients stratified by body weight. There was no significant between group differences in PASI. Diabetes was significantly more common in patients weighing ≥ 80 kg than those weighing < 80 kg (P < 0.05).

Table 2. Psoriasis area severity index (PASI) and comorbidities in patients receiving etanercept treatment for psoriasis, stratified by weight (n = 66).

| Parameter      | Weight <80 kg | Weight ≥80 kg |
|----------------|---------------|---------------|
| PASI Before treatment | 12.19 ± 6.00  | 16.21 ± 12.52 |
| Week 24        | 2.82 ± 3.49   | 4.14 ± 3.80   |
| Week 48        | 1.89 ± 2.30   | 3.38 ± 3.50   |
| Hypertension   | 5 (14.7)      | 7 (21.9)      |
| Type II diabetes | 2 (5.8)      | 5 (15.6)*     |
| Hyperlipidaemia| 4 (11.8)      | 2 (6.2)       |

Data presented as mean ± SD or n of patients (%). *P < 0.05; last-observation-carried-forward analysis.

Data regarding PASI and comorbidities in patients stratified according to BMI are shown in Table 3. After treatment with etanercept for 48 weeks, PASI scores were significantly higher in obese patients than healthy weight or overweight patients (P < 0.001 for each comparison). Type II diabetes was significantly more common in obese patients than healthy weight or overweight patients (P < 0.01 for each comparison).

Discussion

In contrast to the findings of others, 1–3 our data indicate that obesity (BMI ≥ 30 kg/m²) has a negative effect on the efficacy of etanercept for treatment of psoriasis. A high BMI has been shown to be a potential predictor of anti-TNF-α drug discontinuation. 6 The literature regarding the effect of weight/BMI on efficacy is limited: one study had an inadequate sample size, 3 others had a short duration (24 weeks), 2,7 and another stratified patients into two groups only (using BMI 25 kg/m²). 1 Furthermore, the majority of studies have focused on body

Table 3. Psoriasis area severity index (PASI) and comorbidities in patients receiving etanercept treatment for psoriasis, stratified by body mass index (BMI) (n = 66).

| Parameter      | Normal weight a | Overweight b | Obese c   |
|----------------|-----------------|--------------|-----------|
| PASI Before treatment | 12.35 ± 8.1349 | 12.25 ± 5.7551 | 12.61 ± 14.426 |
| Week 48        | 1.72 ± 3.0186   | 1.86 ± 2.8763 | 2.94 ± 2.8123 *** |
| Hypertension   | 3 (9.1)         | 6 (28.6)     | 3 (25)    |
| Type II diabetes | 2 (6.1)        | 1 (4.8)      | 4 (33.3)** |
| Hyperlipidaemia| 2 (6.1)         | 3 (14.3)     | 1 (8.3)   |

Data presented as mean ± SD or n of patients (%). aBMI 22 – 24.99 kg/m². bBMI 25 – 29.99 kg/m². cBMI ≥ 30 kg/m². **P < 0.01, ***P < 0.001 vs both other groups; last-observation-carried-forward analysis.
weight and not BMI.\textsuperscript{8} This may explain the differences between published studies and our experience.

In conclusion, obesity is associated with decreased efficacy of etanercept in psoriasis. Additional, larger scale studies are required to confirm our findings.

**Declaration of conflicting interest**

The authors declared no potential conflicts of interest with respect to the research, authorship, and/or publication of this article.

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