

Relative safety of biological drugs in the maintenance phase in adult patients with moderate to severe plaque psoriasis

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BACKGROUND

Infliximab, adalimumab, etanercept and ustekinumab are indicated to treat moderate-severe plaque psoriasis in Europe.

PURPOSE

To assess the relative safety of biological drugs in the maintenance phase in adult patients with moderate-severe plaque psoriasis.

MATERIAL AND METHODS

A **systematic review** of literature has been conducted focused on the long term safety.

Databases:

until March 2012
MEDLINE
EMBASE
Cochrane Library
Centre for Reviews and Dissemination

Selection criteria:

Health technology agencies reports, bayesian network meta-analyses, systematic reviews, randomized controlled trials (RCTs), non-RCT, and observational studies in patients with moderate-severe plaque psoriasis treated with biologics at the doses approved by the EMA.

The end points evaluated were **mortality, adverse events (AEs), serious AEs and withdrawals due to AEs.**

Two authors independently selected the studies, assessed the quality, and performed the data extraction.

RESULTS

There is no direct evidence neither adjusted indirect comparisons that compared the relative safety of the four biological drugs.

The evidence was obtained from **five systematic reviews.**

Biological agents appear to have a similar safety profile, with a low incidence of serious AEs in eligible psoriasis patients. Biological therapy was well tolerated in long-term treatment, and showed neither dose nor time dependent toxicity.

The rate of patient-years of exposure/follow-up differs significantly between the four drugs. In addition, for drugs launched ahead of time (such as etanercept), safety controls were less stringent.

Based on unadjusted indirect comparisons

- Etanercept has the highest mortality, infectious AEs and non-melanoma skin cancer (non-metastatic cutaneous squamous cell or basal cell carcinoma) rates per 100 patient-years of exposure, followed by ustekinumab and adalimumab, which present similar rates.
- Infliximab presents the highest rate of serious infectious AEs, despite being the biological agent with the shortest follow-up phase.

CONCLUSION

The available evidence is insufficient to suggest differences in safety between the four biological drugs.