

ARE ALL BIOLOGIC AGENTS IN THE TREATMENT OF ANKYLOSING SPONDYLITIS EQUIVALENT ALTERNATIVES?



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BACKGROUND AND IMPORTANCE

Nine drugs are currently approved for the treatment of ankylosing spondylitis (AS) in adults: adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, ixekizumab, secukinumab, upadacitinib and tofacitinib. Tofacitinib was the last of them to receive its approval. However, there are not direct comparisons between them.

OBJECTIVES

To establish whether the drugs approved for AS in adults can be considered equivalent therapeutic alternatives (ATE) in efficacy in AS

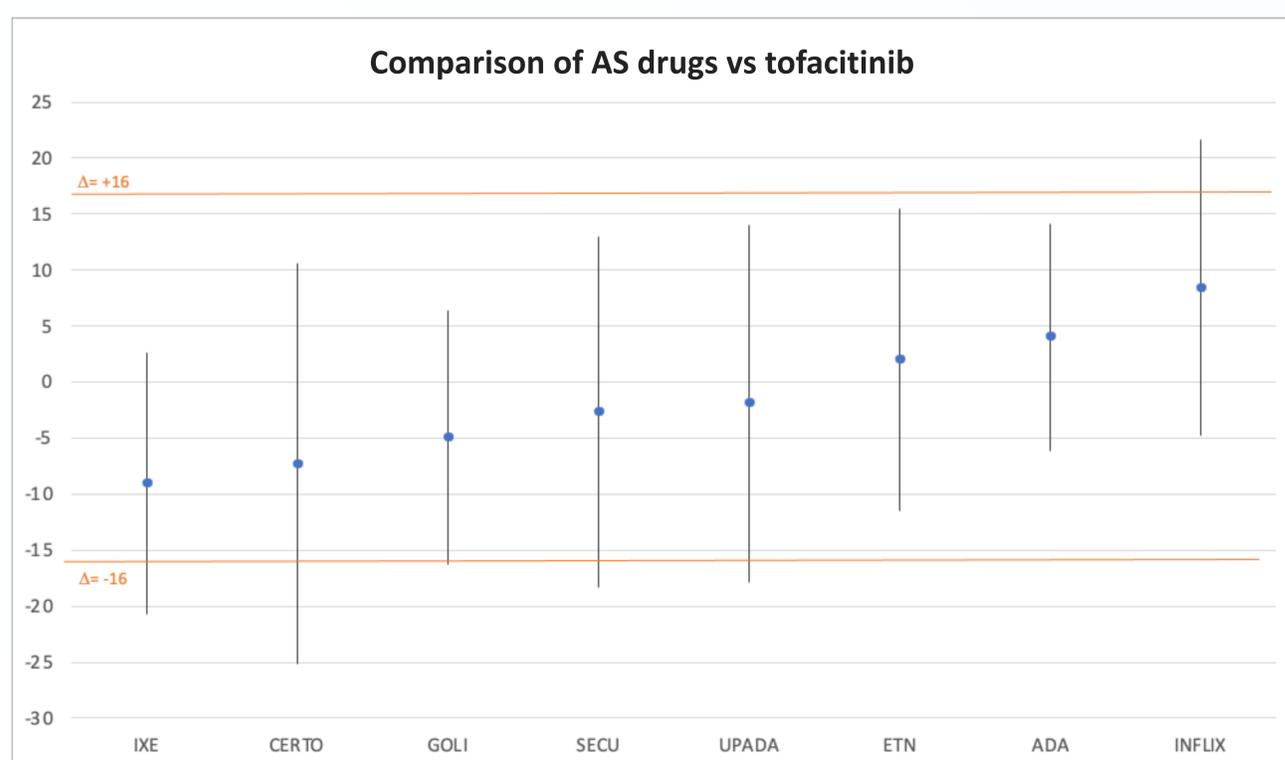
METHODS

A search of clinical trials of these drugs in adult patients with AS was conducted, phase II or III, double-blinded, controlled with other drug or placebo. Other inclusion criteria were:

- Endpoint: ASAS40 (a $\geq 40\%$ improvement and an absolute improvement from baseline of the Assessment in SpondyloArthritis international Society).
- Follow-up time: 12-16 weeks.

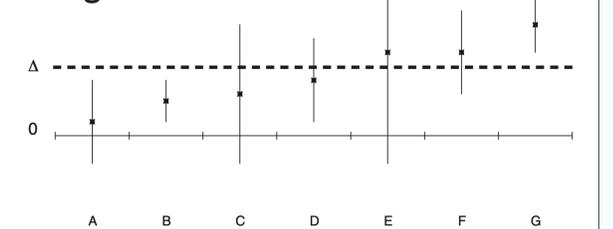
For those drugs with more than one study, a previous meta-analysis was performed using Joaquin Primo calculator. An adjusted indirect comparison (IC) of the drugs used in AS versus tofacitinib was performed using the Bucher method, using Joaquin Primo calculator. Due to lack of data in the literature and considering that therapy failure can be recovered with second lines, half of the ASAS40 value obtained in meta-analysis was taken as delta value (Δ). ATE guide was followed in order to establish a positioning.

RESULTS



Δ = delta value as half of ASAS40 obtained in meta-analysis.

ATE guide



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- A. Statistical and clinical equivalence.
- B. Clinical equivalence (irrelevant difference).
- C. Probable clinical equivalence.
- D. Probably irrelevant difference.
- E. Possible relevant difference.
- F. Probably relevant difference.
- G. Relevant difference (not ate).

CONCLUSION AND RELEVANCE

Tofacitinib and the rest of these drugs could be considered ATE. For a definitive statement, the criteria of safety and adequacy should be considered.

