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Title **Infliximab and Etanercept in Rheumatoid Arthritis: Systematic Review of Long-Term Clinical Effectiveness, Safety, and Cost Effectiveness**

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Aim

To review the available data on the long-term effectiveness, safety, and cost effectiveness of infliximab (IFX) and etanercept (ETN) in treating patients with rheumatoid arthritis (RA).

Conclusions and results

Randomized controlled trials (RCTs) of >1 year duration showed that anti-TNF agents have a small to moderate effect in clinical outcomes. A clinical and significant improvement in American College of Rheumatology improvement criteria (ACR50) and Disease Activity Scores (DAS28) was observed for IFX+methotrexate (MTX) and ETN+MTX, compared with MTX alone. A statistically significant pooled result was observed for the Short Form 36 (SF-36) physical component with IFX 3 mg/kg every 8 weeks, but the effect was not clinically meaningful (1.77, with an effect size of 0.15). The beneficial effects of anti-TNF agents were revealed on radiological progression: Significant differences were observed between the treatment and control groups, even when the clinical differences were not significant. ETN alone did not offer a clear benefit over MTX alone, but ETN+MTX was better than MTX alone. Anti-TNF agents are well tolerated in the short term (generally ≤6 months), but there are concerns about their longer-term safety. Economic evidence suggests that treatment with ETN and IFX, each used concomitantly with MTX, is only cost effective in treating RA after the failure of other disease-modifying anti-rheumatic drugs (DMARDs), and if a high threshold for cost effectiveness is used (>100 000 Canadian dollars per quality-adjusted life-year (QALY)).

Recommendations

Not applicable.

Methods

The literature was systematically reviewed to compare IFX and ETN at recommended dosages with placebo or other therapies. Outcome measures included American College of Rheumatology improvement criteria (ACR-50: 50% improvement in the number of swollen and tender joints, and 50% in at least 3 of the other 5 core set measures), Disease Activity Scores, functional status, and radiological progression. A meta-analysis was performed to synthesize and combine the results of RCTs. Data from observational studies were synthesized, but not combined. For the review of cost effectiveness, we included all studies reporting costs and outcomes.

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