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Head-to-head trial shows abatacept is as effective as adalimumab in patients with active rheumatoid arthritis

Subcutaneous abatacept achieved similar efficacy with fewer discontinuations as a result of adverse events compared to adalimumab in patients with active rheumatoid arthritis, according to results from the first 2-year head-to-head trial to compare biologics.

The two biologics have different modes of action. Abatacept reduces the co-stimulation of T-cells, in turn reducing activation of other cells in the inflammatory process, while adalimumab is a TNF blocker.

The AMPLE study randomized 646 biologic-naïve patients with active rheumatoid arthritis and an inadequate response to methotrexate to either abatacept (125 mg weekly, without an intravenous load) or adalimumab (40 mg biweekly), with a stable dose of methotrexate. Of 318 abatacept patients, 252 (79.2%) completed the trial, as did 74.7% (245 of 328) of adalimumab patients.

AMPLE met its primary end point as measured by non-inferiority of ACR20 (American College of Rheumatology 20% improvement) at year one, with comparable efficacy for the abatacept regimen (64.8% ACR20 responders) as for adalimumab-based treatment (63.4%). This efficacy continued to year two with 60% of patients achieving ACR20 in both treatment groups.

Professor Michael Schiff, Clinical Professor of Medicine, University of Colorado, USA

Radiographic progression was similar, with 85% of patients on the abatacept regimen and 84% of those on the adalimumab regimen achieving radiographic non-progression at 2 years.

Reporting the results, lead author Professor Michael Schiff from the University of Colorado, USA, said: 'This robust data set demonstrates that subcutaneous abatacept and adalimumab are equally efficacious in clinical, functional and radiographic outcomes. This study is a great leap forward for patients as it shows another treatment is as effective as adalimumab.'

Further results showed onset of response was generally similar for the two treatment groups. They also showed similar rates of adverse events and serious adverse events in the abatacept and adalimumab groups (13.8% *vs* 16.5%) and malignancies (2.2% *vs* 2.1%). More autoimmune adverse events occurred with abatacept (3.8% *vs* 1.8%); none were serious. Injection site reactions occurred less frequently (4.1% *vs* 10.4%), and there were fewer discontinuations as a result of adverse events, serious adverse events and serious infections in the abatacept group compared to the adalimumab-treated patients.

Susan Mayor

Dutch study reveals high rate of NSAID use in at-risk patients

One in eight patients at risk of developing a serious adverse drug event with non-steroidal anti-inflammatory drugs (NSAIDs) is taking them over-the-counter, often to treat a musculoskeletal complaint, warned a Dutch study (Koffeman et al, 2013).

Researchers studied adult patients registered with four GPs in the Netherlands. They looked at two different patient populations: a random sample of adults and a sample of adults at high risk for developing a serious adverse event from taking over-the-counter NSAIDs based on their medical records. The high-risk group included people with a history of a peptic ulcer or ulcer complication, myocardial infarction, stroke or heart failure, aged over 70 years, glomerular filtration rate <30 ml/litre, or two or more of the following: use of an anticoagulant, aspirin, corticosteroid or selective serotonin-reuptake inhibitor; age 60–70 years; history of severe rheumatoid arthritis or diabetes mellitus.

Patients were sent a questionnaire asking about their use of over-the-counter NSAIDs in the previous 4 weeks. One in eight (13%) of the 265 high-risk patients who took part reported taking an over-the-counter NSAID. More than one-third of these had taken the medication for longer than 7 days and 3% had exceeded the maximum recommended daily dose. In the general population sample, 29% of the 120 patients taking part had used an over-the-counter NSAID.

'NSAIDs tend to be regarded by patients as harmless painkillers. However, in reality, even those available over-the-counter can cause a number of unpleasant side effects,' said lead author Aafke Koffeman of the Erasmus Medical Center, Rotterdam, Netherlands.

'These new data highlight the importance of health-care professionals continuing to inform their patients of the risks of taking over-the-counter NSAIDs, particularly where a new diagnosis or prescription increases their individual risk. High-risk patients with painful musculoskeletal complaints should be advised to take safer alternative painkillers,' she concluded.

Susan Mayor

Koffeman A et al (2013) Use of over-the-counter non-steroidal anti-inflammatory drugs in the general population and in patients with a high risk of adverse drug events. EULAR Annual European Congress of Rheumatology; 12–15 June, Madrid, Spain. Abstract no OP0202-PC