National Institute for Health and Clinical Excellence

Adalimumab, Etanercept and Infliximab in the treatment of Ankylosing Spondylitis

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Introduction

With a membership of over 390,000 registered nurses, midwives, health visitors, nursing students, health care assistants and nurse cadets, the Royal College of Nursing (RCN) is the voice of nursing across the UK and the largest professional union of nursing staff in the world. The RCN promotes patient and nursing interests on a wide range of issues by working closely with Government, the UK parliaments and other national and European political institutions, trade unions, professional bodies and voluntary organisations.

Response to the Assessment Report on the use of Anti-TNFa therapies for the treatment of Ankylosing Spondylitis (AS)

The Royal College of Nursing welcomes the opportunity to review this document. This comprehensive report has reviewed the evidence available on three anti-TNFa therapies (adalimumab, etanercept and infliximab).

The interpretation of the evidence base, particularly with regard to the clinical effectiveness

The research evidence has been thoroughly outlined and discussed and it is recognised that more research is necessary to fully inform on the treatment of AS in the context of anti-TNFa therapies, particularly in relation to the long-term risks and benefits /outcomes for anti-TNFa therapies.

However, as the report emphasises, this crippling disease has immense implications for these relatively young individuals of working age. Presently there is no effective
treatment for AS and biologic therapies such as Anti-TNFα have provided significant benefit and hope to many who are severely incapacitated by this disease, particularly those losing their employment, social status and family life.

Relevant evidence that has been left out

How should the clinical results be interpreted in the context of current clinical practice?
At present the vast majority of patients with AS are treated with Non-steroidal anti-inflammatory drugs, physiotherapy and occasional disease modifying anti-rheumatic drugs if they have peripheral arthritis – there is little evidence that these treatments are effective in preventing joint/spinal damage in AS (Ferraz et al 1990, Dougados et al 1995, Marshall et al 2001). At long last we have a treatment that is effective at reducing the pain, stiffness and damage for AS patients, patients who are treated with the anti TNFα therapy have regained their lives, often staying in work instead of retiring due to ill health and even in some cases giving up claiming sick benefits and going back to work. The BSR register has data on patients with AS who have had this therapy over the past three years and should be able to share their evidence with the NICE Appraisal Committee.

There have been several abstracts presented at national and international Rheumatology meetings over the past three years which have gone some way to indicate the number of patients who would qualify for anti TNFα therapy utilising the BSR guidelines. Whilst many people with AS can maintain a normal life with the use of NSAIDs and regular physiotherapy in the form of hydrotherapy, it is increasingly difficult to access hydrotherapy for these patients due to recent cutbacks within the NHS.

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The assumptions underlying the economic model
It is very difficult to comment on the economic model when we are clinicians and not statisticians.

Although this is a hypothetical point - there are important lessons to be learnt from experiences in the treatment of Rheumatoid Arthritis for anti-TNFα therapies where there is now increasing evidence that we should be treating newly diagnosed patients with anti-TNFα early and aggressively, particularly as there appears to be significant benefits in reducing joint damage. The patients seen in these studies were not the newest and perhaps youngest of AS patients – reflecting those with established severe disease. This may mean that an important window of opportunity in ensuring individuals maintain their employment (evidence suggests those that are on incapacity benefit for more than 6 weeks do not return to work).

The ethical issues of denying patients these treatments when there are no other options available to them needs be carefully considered. It is hoped that a research based approach to providing treatment could be considered, perhaps in a model that is similar to that of the British Society for Rheumatology Register – where a working group could identify treatment criteria, the risk/benefit of treatment criteria and evaluate switching and ultimately long term benefits which would include work related and societal issues.

Although only a very small study with a few patients, some of us have been personally involved in mapping patient’s journeys with RA and note with interest that patients who have an established aggressive disease have higher costs than other patients with long term conditions (excluding their anti-TNFα treatment). We would like to see an economic evaluation of these patients to explore whether there are similar issues for AS patients. We still fail to adequately assess the costs to the individual in all analysis – as in our mapping studies these costs to the individual exceeded the costs to healthcare. However this further research should not preclude patients with AS from accessing the appropriate treatment – NSAIDs, hydrotherapy, physiotherapy and ultimately biologic therapy.

The costs for infliximab infusions is likely to be significantly reduced in the next few years with many private providers and innovative approaches to delivering more intravenous infusions in the community. It is also a valuable option for those who are
unable to administer subcutaneous injections. Patients should also be provided with a choice based within a specific framework of assessment and need.

**General**

The report though comprehensive, was in parts unwieldy and difficult to wade through. It would be useful to have a report that is easier to digest.
References


**Brunner F et al** (2006) Ankylosing spondylitis and heart abnormalities: do cardiac conduction disorders, valve regurgitation and diastolic dysfunction occur more often in male patients with diagnosed AS for over 15 years than in the normal population? *Clin Rheum* 25 (1) p24-9


**Karberg et al** (2005) Bone loss is detected more frequently in patients with ankylosing Spondylitis with syndesmophytes *J Rheumatal* 32 (7) P1290-8


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