BSR and BHPR guideline for the treatment of axial spondyloarthritis (including ankylosing spondylitis) with biologics

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Key words: ankylosing spondylitis, axial spondyloarthritis, anti-TNF, biologic, guideline, treatment

Executive Summary

Scope and purpose
Axial SpA (axSpA) is a chronic inflammatory condition predominantly involving the spine and sacroiliac joints (SIJ), with or without extra-scapal manifestations including peripheral arthritis, enthesitis, iritis, psoriasis and IBD. Individuals with axSpA experience significant pain, stiffness and lack of function that translates into important health care costs and increased mortality.

AxSpA can be classified into two subgroups: radiographic axSpA, commonly referred to as AS, and non-radiographic axSpA (nr-axSpA). The primary difference between these two subgroups is the presence or absence of defined structural changes in the SIJ as detected on plain radiography. Although patients with nr-axSpA do not fulfil the modified New York criteria for AS [1], their burden of disease is similar [2] and they may derive as much benefit from treatment as patients with established AS. This revision of the 2005 BSR guidelines [3] provides evidence-based guidance for UK clinicians prescribing biologic drugs for adult patients across the spectrum of axSpA. This includes the criteria for starting treatment, the

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choice of drug and assessing response to treatment. Peripheral spondyloarthritides and juvenile SpA are outside the scope of these guidelines, and readers are referred to the BSR 2012 guidelines for the management of PsA [4].

Key recommendations

These recommendations are summarized in a treatment algorithm (Fig. 1). Accompanying descriptions of evidence and full recommendations are given in the full guideline, provided as supplementary data, available at Rheumatology Online.

The effectiveness of biologics in axSpA

(i) Anti-TNF therapy is effective at reducing disease activity and spinal pain in axSpA. While short-term MRI data support the efficacy of anti-TNF therapy in treating inflammatory SIJ and spinal lesions in axSpA, evidence for anti-TNF therapy on radiographic disease progression is currently limited [level of evidence (LOE) 1+; strength of recommendation A; consensus score 9.6].

(ii) Currently there is insufficient evidence to recommend the use of other biologic agents in axSpA (LOE 1+; strength of recommendation B; consensus score 9.3).

Initiating treatment

(i) Patients should be considered for anti-TNF therapy if they have active axSpA (LOE 1+; strength of recommendation B; consensus score 9.6).

(ii) Active disease is defined as a BASDAI and spinal pain visual analogue scale (VAS) score ≥ 4 despite standard therapy (LOE 1+; strength of recommendation B; consensus score 8.5).

(iii) The BASDAI should be measured on two occasions at least 4 weeks apart. Current National Institute for Health and Care Excellence guidelines require patients to have active spinal disease on two separate
occasions 12 weeks apart, with the aim of avoiding the overtreatment of patients with a short-lived flare of disease. However, as flares in AS last for an average of 2–3 weeks [5], an interval of 4 weeks between scores is sufficient and should not delay treatment unduly (LOE 2+; strength of recommendation C; consensus score 7.2).

(iv) Patients with active disease who do not meet modified New York criteria for AS should also have had a positive MRI and/or raised CRP. Prescribers should be confident that worsening symptoms, radiological changes and raised inflammatory markers are due to axSpA and not to other pathology such as malignancy or infection. Discussion with an axSpA specialist should be considered before starting treatment in a patient with nr-axSpA and no SIJ bone marrow oedema on MRI (LOE 1+; strength of recommendation B; consensus score 9.3).

Choice of Drug

(i) Extra-articular manifestations and patient choice should be considered when selecting an anti-TNF agent. In the absence of head-to-head studies, systematic reviews have shown no statistical difference in efficacy between infliximab, golimumab, etanercept and adalimumab in the treatment of AS (certolizumab data were not included in these comparative reviews, but its efficacy has been established in clinical trials). There are insufficient data to comment on relative efficacy in nr-axSpA. However, not all biologics are licensed for or effective in the treatment of extra-articular disease, so drug choice should take into account comorbidities and the preferred route and frequency of administration (LOE 4; strength of recommendation D; consensus score 8.9).

Assessing Response

(i) Initial efficacy response should be assessed following 3–6 months of therapy and responders should then be reassessed every 6 months (LOE 2+; strength of recommendation D; consensus score 8.6).

(ii) Response is defined as a reduction in the BASDAI and spinal pain VAS of $\geq 2$ U from baseline (LOE 1+; strength of recommendation B; consensus score 8.3).

(iii) If, because of cognitive or communication difficulties, the BASDAI cannot be used to monitor disease activity, the decision to initiate and continue therapy should be based on the treating clinician’s assessment of disease activity (LOE 4; strength of recommendation D; consensus score 9.9).

Withdrawal of Therapy

(i) In the absence of an initial clinical response by 6 months, or failure to maintain response at two consecutive assessments, withdrawal of that anti-TNF agent should be considered (LOE 4; strength of recommendation D; consensus score 9.4).

(ii) There is no evidence to support the withdrawal of anti-TNF therapy in treatment responders (LOE 2+; strength of recommendation B; consensus score 9).

Switching

(i) In the event of anti-TNF failure due to inefficacy or adverse events, an alternative anti-TNF agent should be offered if clinically appropriate (LOE 2+; strength of recommendation C; consensus score 9.7).

Safety

The safety of anti-TNF therapies in axSpA is comparable to other inflammatory joint diseases such as RA. There is little evidence to suggest that safety issues differ hugely with different disease groups, and the 2010 British Society for Rheumatology (BSR) guidelines on the safety of anti-TNF therapies in RA are applicable in axSpA [6].

Funding: No specific funding was received from any bodies in the public, commercial or not-for-profit sectors to carry out the work described in this summary.

Disclosure statement: L.H. has received unit funding from AbbVie, MSD, Pfizer and UCB, was sponsored to attend a meeting by MSD and has received a research grant from Pfizer. G.J. has received unit funding from Pfizer and AbbVie and an honorarium from AbbVie. D.Mu. was sponsored to attend a meeting by MSD, has received honoraria from UCB and AbbVie and sits on an advisory board for AbbVie. R.S. is in receipt of research grants from Pfizer and AbbVie, has been sponsored to attend educational meetings by AbbVie and Novartis and has received honoraria from AbbVie, Novartis, Pfizer, UCB and MSD. N.B. has received unit funding from Novartis, was sponsored to attend a meeting by AbbVie and has received speaker fees from Pfizer and UCB. K.G. has received research grants and speaker fees from AbbVie, Pfizer, MSD, UCB and Novartis. S.S. has received research unit funding from Pfizer and Janssen; speaker fees from AbbVie, Pfizer, Amgen, UCB, Janssen, Novartis and MSD; honoraria or consultancies from BMS, MSD, AbbVie, UCB, Roche, Pfizer, Janssen, Boehringer Ingelheim and Novartis and has been sponsored to attend meetings by AbbVie, Janssen, UCB and MSD. K.R.M. is the lead organiser of the Rheumatology Education Symposium for General Practitioners, run by the Peninsula Rheumatologists, which has received a yearly educational grant of £4500 from AbbVie for the last 6 years and the Torbay Rheumatology Department has received a grant from AbbVie for a Mindfulness project. H.M.-O. has received honoraria from and acted as a consultant for AbbVie, Celgene, Novartis, UCB, Janssen and Pfizer and has received study grants from Janssen and Pfizer. D.Ma.
has received honoraria from MSD, Pfizer, Wyeth, UCB and Celgene. L.v.R. has received honoraria and research support from Pfizer and AbbVie. The other authors have declared no conflicts of interest.

Supplementary data

The full guideline is available at Rheumatology Online and an audit tool to assess compliance with these recommendations can be found on the BSR website.

References