The 2012 BSR and BHPR guideline for the treatment of psoriatic arthritis with biologics

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Key words: psoriatic arthritis, biologics, treatment, management, guidelines, recommendations, anti-TNF therapies, psoriasis, enthesitis, dactylitis.

Executive summary

Background of the disease
PsA is a chronic inflammatory arthropathy affecting up to 40% of patients with skin or nail psoriasis. It is considered a type of seronegative spondyloarthritides and can cause arthritis, enthesitis, dactylitis and axial inflammation. The use of anti-TNF therapy for the treatment of inflammatory arthritis, including PsA, has revolutionized therapeutic options in rheumatology.

Need for guidelines
The last British Society of Rheumatology (BSR) guidelines for the treatment of PsA were published in 2005 when anti-TNF therapy was not widely available. At that time only one of the anti-TNF therapies was licensed for the treatment of PsA. Since then, their use in PsA has become more widespread, with multiple anti-TNF drugs licensed for the treatment of PsA and approved for therapy by the National Institute for Health and Clinical Excellence (NICE). However, despite these advances, there are still patients...
who do not respond to treatment with anti-TNF therapies and there are difficult clinical situations where the risks of such drugs may outweigh the benefits of therapy. For this reason, it was felt that further guidance was required.

Objectives of the guidelines
These guidelines offer systematic and evidence-based recommendations for the prescription of anti-TNF therapies in adult PsA patients to support UK clinicians in their use. The guidelines cover adult patients with PsA affecting all domains of psoriatic disease. They provide a stepwise management plan giving clear advice on treatment from the initial diagnosis, including inclusion/exclusion criteria for treatment, monitoring requirements and how to quantify response to biologics. They provide evidence-based advice for the use of anti-TNF therapies in difficult situations including pregnancy and significant comorbidities.

Target audience
The guidelines have been developed to provide assistance to rheumatologists and other clinicians involved in the prescription of anti-TNF therapies for psoriatic disease. They will also assist specialist nurses and allied health professionals (AHPs) in the application, assessment and monitoring of treatment.

These guidelines do not include
(i) Biologic therapies for JIA.
(ii) Biologic therapies for patients with psoriatic disease confined to the skin.

The key recommendations from the guidelines with reference to the management algorithm

Peripheral arthritis
(i) Anti-TNF therapy should be considered for those patients with active arthritis (defined as at least three tender and three swollen joints) who have failed treatment with at least two conventional DMARDs. Anti-TNF therapy may be considered for patients who have failed only one DMARD, especially where there is evidence of any of the following adverse prognostic factors. Five or more swollen joints in association with elevated CRP persisting for >3 months or structural joint damage due to disease (Grade C) (Fig. 1). Consensus score 9.6.

(ii) All of the licensed anti-TNF therapies are recommended for use in patients eligible for treatment and the choice of therapy should be left to the treating physician after considering concomitant medical problems, patient preference and cost-effectiveness. For patients requiring rapid control of skin psoriasis, infliximab or adalimumab are preferred in accordance with the British Association of Dermatology (BAD) guidelines [1] (Grade A). Consensus score 9.9.

(iii) Anti-TNF therapies should be continued in patients who have responded after 3 months of treatment. In the case of non-responders, consideration should be given to a further 12 weeks of therapy if there has been a partial response and then continuing therapy if there has been a full response compared with baseline (Grade B). Consensus score 9.

(iv) Anti-TNF therapies should be considered in patients with severe persistent oligoarthritis (fewer than three tender/swollen joints), which has a major demonstrable influence on well-being and who have failed treatment with at least two conventional DMARDs and appropriate intra-articular therapy (Grade C). Consensus score 9.2.

Axial disease
(i) Anti-TNF therapy should be considered for those patients with active axial PsA according to the 2010 update of the Assessment of SpondyloArthritis FIG. 1 Treatment algorithm for anti-TNF therapy in PsA.
Response measures

(i) The psoriatic arthritis response criteria (PsARC) are recommended as the clinical response criteria for peripheral PsA and a psoriasis area severity index (PASI) score should be completed for patients with significant skin psoriasis in collaboration with a dermatologist. In the future, following appropriate validation, static composite measures evaluating all aspects of psoriatic disease should ideally be used to assess eligibility and response in PsA (Grade A). Consensus score 9.2.

Safety—infections

(i) Anti-TNF therapy should not be initiated or continued in the presence of serious active infection, but can be recommenced once the infection has resolved clinically (Grade B). Anti-TNF therapy should be used with caution in patients at high infection risk after discussing the relative risks and benefits (Grade C). Consensus score 9.8.

(ii) Patients on anti-TNF therapy should be informed of the possibility of atypical or opportunistic infections and treatment should be stopped and advice sought in suspected cases (Grade B). Consensus score 9.7.

(iii) Anti-TNF therapy in those with chronic HBV should be approached with caution given the potential risk of reactivation and fulminant hepatitis. Anti-TNF therapy should only be commenced in those with well-controlled disease, with appropriate antiviral treatment and regular monitoring in collaboration with a hepatologist. Consideration should be given to vaccinating those at risk of HBV prior to treatment (Grade C). Consensus score 9.5.

Safety—tuberculosis

(i) Prior to starting treatment with anti-TNF therapy, all patients should be screened for mycobacterial infection in accordance with the latest national guidelines. Active mycobacterial infection should be adequately treated before anti-TNF therapy is started. Prior to starting anti-TNF therapy, prophylactic anti-tuberculosis (TB) therapy (as directed by the latest national guidelines) should be given to patients with evidence of potential latent disease (Grade B). Physicians should be vigilant for the development of mycobacterial infections throughout treatment with anti-TNF and for at least 6 months after discontinuation (Grade C). If patients develop evidence of mycobacterial infection while on anti-TNF therapy, they should receive a full course of anti-mycobacterial chemotherapy—the anti-TNF therapy may be continued during this time if clinically indicated (Grade C). Consensus score 9.4.

Safety—HIV and hepatitis

(i) Patients at risk should be screened for HIV, HBV and HCV prior to anti-TNF therapy (Grade C). Consensus score 9.3.

(ii) HIV or HCV infection should not preclude treatment with anti-TNF therapy, although treatment should only be commenced in those with well-controlled disease and with appropriate monitoring under the care of a hepatologist or HIV specialist (Grade B). Consensus score 8.9.

(iii) Anti-TNF therapy in those with chronic HBV should be approached with caution given the potential risk of reactivation and fulminant hepatitis. Anti-TNF therapy should only be commenced in those with well-controlled disease, with appropriate antiviral treatment and regular monitoring in collaboration with a hepatologist. Consideration should be given to vaccinating those at risk of HBV prior to treatment (Grade C). Consensus score 9.5.

Safety—malignancy

(i) Anti-TNF therapy should be avoided in patients with a current or prior history of malignancy unless the malignancy was diagnosed and treated >10 years ago and/or where the likelihood of cure is high. All patients should be encouraged to participate in national cancer screening programmes appropriate for their age and gender. Patients on anti-TNF should be regularly screened for skin cancers (including melanoma), especially if their background risk is high, and patients who develop suspicious skin lesions while on TNF therapy should be referred for urgent dermatological review and management. Anti-TNF therapy is relatively contraindicated in patients who have had prior treatment with >150 psoralen + UVA (PUVA) and/or >350 UVB treatments, especially when this has been followed by treatment with ciclosporin and should be formally reviewed by a dermatologist where therapy cannot be avoided (Grade C). Consensus score 9.4.

Safety—pregnancy

(i) Anti-TNF agents should ideally be stopped prior to pregnancy and restarted after the end of lactation or delivery if not breastfeeding. Management should be in accordance with BSR guidelines for RA and the BAD guidelines (Grade C). Consensus score 9.3.

What to do if anti-TNF fails?

(i) In the case of failure of an anti-TNF treatment either due to inefficacy or adverse events, an alternative anti-TNF therapy should be considered and response to treatment assessed as for the first anti-TNF agent. Consideration of the possible consequences for control of skin disease should be given and shared care with a dermatologist when appropriate (Grade B). Consensus score 9.5.

Disclosure statement: W.T. has received research funding and/or honoraria from Abbott and Pfizer. L.C. has received honoraria and/or funding for clinical trials from...
Abbott, MSD, Pfizer and UCB. N.J.M. has received honoraria from Pfizer and UCB for participation in advisory board meetings and unrestricted grant support from Abbott and Pfizer. S.K. has received honoraria from Abbott, MSD, Pfizer and Chugai-Roche. I.B.M. has received honoraria and research support from Pfizer, UCB, Janssen, BMS and MSD. P.H. has served in an advisory capacity and received honoraria from Abbott, Pfizer, Celgene, MSD, Roche and UCB. S.O. has received honoraria from Abbott, Astra Zeneca, Chugai Roche, Pfizer, Roche, Servier and UCB. A.O. has served on a data monitoring committee for Amgen and received research support from Merck and Abbvie. E.K. has received honoraria from Abbott, Pfizer and UCB. N.W. has received honoraria from Abbott. All other authors have declared no conflicts of interest.

Supplementary data
Full guidelines are available as supplementary data at Rheumatology Online.

References