
Implementing the findings of the TICOPA trial in clinical practice: challenges in implementation and how information technology can bridge the gap

L.C. Coates

Leeds Institute of Rheumatic and Musculoskeletal Medicine, University of Leeds, Leeds, UK and Leeds Musculoskeletal Biomedical Research Unit, Leeds Teaching Hospitals NHS Trust, Leeds, UK.

Laura C. Coates, MBChB,
MRCP (UK), PhD

Please address correspondence to:

Dr Laura C. Coates,
Leeds Institute of Rheumatic and Musculoskeletal Medicine,
University of Leeds, 2nd Floor,
Chapel Allerton Hospital,
Harehills Lane,
Leeds LS7 4SA, United Kingdom.
E-mail: l.c.coates@leeds.ac.uk

Received and accepted on September 20, 2016.

Clin Exp Rheumatol 2016; 34 (Suppl. 101): S73-S74.

© Copyright CLINICAL AND EXPERIMENTAL RHEUMATOLOGY 2016.

Key words: psoriatic arthritis, treat-to-target, IT systems, treatment, management

Funding: The research is supported by the National Institute for Health Research (NIHR) Leeds Musculoskeletal Biomedical Research Unit. The views expressed are those of the author(s) and not necessarily those of the NHS, the NIHR or the Department of Health.

Competing interests: the author declares a potential conflict of interest having received grant support and/or honoraria for consultations and/or for presentations as indicated: LC Coates: Abbvie, Amgen, Boehringer Ingelheim, Celgene, Janssen, Lilly, MSD, Novartis, Pfizer, Sun Pharma, and UCB.

ABSTRACT

As in rheumatoid arthritis, treating to target in psoriatic arthritis (PsA) has been shown to improve outcomes over standard therapy. As a result of this, the European League Against Rheumatism (EULAR) updated recommendations for the management of PsA now recommend a treat-to-target approach for all patients with PsA. However, translating the results of this research remains challenging in clinical practice. Prolonged consultation time associated with implementing this into practice can be minimised using a simple to calculate but inclusive target for treatment and assessing this within information technology (IT) systems. IT systems can combine physician and patient-reported outcomes, use algorithms to calculate any target and even be used to suggest follow up times based on previous data. Utilising these tools can help to make optimal treatment of arthritis feasible in routine clinical practice.

Introduction

The concept of “treat-to-target” was first established in non-rheumatological conditions such as diabetes and hypertension, but it has been established as the optimal management for rheumatoid arthritis (RA) much earlier than in other inflammatory arthritides. The first treat-to-target study in RA was the TICORA study published in 2004 (1). This was followed by further studies utilising the concept of treating to target and it was then established in EULAR treatment recommendations in 2010 (2). Even in RA, adoption of the treat-to-target approach in routine clinical practice has taken time to be widely implemented and still remains limited in uptake.

In 2015, the Tight Control of PsA (TICOPA) trial confirmed the benefits of treating to target in PsA as it became the first treat-to-target study in

the spondyloarthropathies. In PsA, the TICOPA trial was the first to demonstrate improved clinical and patient-reported outcomes with a treat-to-target approach in PsA consisting of 4-weekly review and escalation of treatment aiming for the minimal disease activity (MDA) criteria (3). This measure requires achievement of 5 of the 7 following criteria: tender joint count ≤ 1 ; swollen joint count ≤ 1 ; psoriasis area and severity index ≤ 1 or body surface area ≤ 3 ; enthesitis count ≤ 1 ; Patient global score ≤ 20 ; Patient pain score ≤ 15 ; health assessment questionnaire ≤ 0.5 (4). Following the publication of the TICOPA trial in 2015, the first recommendation of the 2015 European League Against Rheumatism (EULAR) Recommendations for the management of PsA is that “treatment should be aimed at reaching the target of remission or, alternatively, minimal/low disease activity, by regular monitoring and appropriate adjustment of therapy” (5). However, the translation of this approach into clinical practice has raised potential issues about feasibility and it has not been adopted in most centres (6).

Starting to implement a treat-to-target approach in practice has raised two key issues in feasibility. Firstly, introducing a treat-to-target approach generally causes a more rapid escalation of therapy and more treatment changes which in itself may increase appointment times. Whilst this is the key to the improved outcomes, it does concern physicians in busy clinical practice when trying to implement this approach. Secondly, the requirement to measure a target with physician and patient assessed outcome measures of multiple domains of the disease may add time to the consultation.

PsA is a heterogeneous condition with involvement in multiple musculoskeletal and skin domains (7). Optimal care for patients must address all of the man-

ifestations of the disease, not solely the peripheral arthritis. Whilst this comprehensive assessment of disease activity is required to ensure that treatment is optimised for all individuals despite their disease pattern, it does put a potential pressure on implementation of a treat-to-target approach in PsA. All potential targets that could be utilised in PsA include a combination of patient and physician completed outcomes, sometimes with an acute phase marker such as a C-reactive protein (CRP). These measures are then combined mathematically with varying complexity to be used as a composite target, but this must be done within the consultation to allow a treatment decision to be made.

An ideal target should include assessment of as many as possible of the musculoskeletal and skin domains to ensure that disease in all domains is considered, whilst keeping the assessment feasible. The inclusion of an acute phase response such as CRP introduces further complexity and a delay if no recent blood results are available. Waiting for a new acute phase result will delay the assessment of a target and may prevent the decision of treatment changes in the clinic appointment. Finally, although information technology solutions for complex formulae are available (*e.g.* web-based solutions or Apps), most physicians prefer simpler measures to calculate. For these reasons, the TICOPA trial used the MDA criteria which incorporates measures of arthritis, skin disease and enthesitis, does not require a laboratory measure of acute phase response and relies on a simpler calculation (4).

In the TICOPA trial, the MDA criteria were assessed using paper case report forms and calculations of the individual measures (*e.g.* the psoriasis area and severity index) and the final MDA result was done by the physicians on paper. This introduces possible inaccuracies and increases the time taken for assessment in clinic, related to calculating scores and inputting data.

Moving forward from the TICOPA trial, we are aiming to integrate the treat-to-target approach into our routine PsA clinic as well as embedding research. We are planning a research integrated clinic which will implement a

treat-to-target approach for all consenting patients. This approach will utilise electronic data capture and contemporaneous calculations to facilitate the approach and manage time effectively.

As with an increasing number of other clinics worldwide, we plan to use electronic data entry for patient-reported outcomes so that patients can complete their questionnaires before the visit and that these can be automatically incorporated into the database. Some clinics such as the DEPAR database in the Netherlands allow patients to enter data a week or two before their appointment with email reminders. Other clinics such as those using the Go Treat IT system in Norway use tablets or computer screens in the waiting room to input the patient data.

Once patients are reviewed by their treating physician, the physician-assessed measures can be directly inputted to the system and the computer programming can use both the patient and physician completed measurements to calculate the composite target.

In the clinic, our plan moving forward will utilise MDA in daily practice as it represents the best balance between inclusion of multiple domains but feasibility in practice. For flexibility in practice, the MDA criteria can be used with a variety of outcome measures in the skin and enthesitis domains. Within clinical practice we propose to calculate it using the body surface area for the skin component as this is the quickest assessment tool to use and is the easiest for training of non-experienced rheumatologists (6). For similar feasibility reasons, we are proposing the use of the Leeds enthesitis index as this only includes 6 sites for enthesal assessment which can easily be done alongside the 68/66 joint count (6). Indeed, whilst a full assessment of these measures is likely to be informative for the physician, there is an argument with a measure such as MDA that only the cut points need to be assessed. If there are two or more active joints or entheses, or more than 3% body surface area with psoriasis, then the patient will not meet that cut point and treatment escalation should be considered.

The EULAR recommendations have not specified exactly how regularly

patients should be reviewed when implementing a treat-to-target approach in clinical practice (5). Rather than the four weekly review in the TICOPA trial, they suggest assessment of the target every 3-6 months which seems reasonable for the majority of patients once their disease is stable. While we would suggest waiting 12 weeks for review after starting a new therapy to allow it time to work, we otherwise plan to continue with 4 weekly visits until the patient is in consistent MDA for at least 3 visits. At this time, visit frequency would be decreased stepwise to 3-monthly and then 6-monthly, once we are sure disease is stable.

It is now accepted best practice to use this treat-to-target approach although many further research questions remain about optimal targets and optimal treatment choices within the regime. However, the biggest barrier to routine implementation is feasibility with medical professionals struggling in short appointments to do these comprehensive assessments and escalate therapy. Using information technology may help to deal with the feasibility concerns surrounding treat-to-target in clinical practice allowing optimal management for patients.

References

1. GRIGOR C, CAPELL H, STIRLING A *et al.*: Effect of a treatment strategy of tight control for rheumatoid arthritis (the TICORA study): a single-blind randomised controlled trial. *Lancet* 2004; 364: 263-9.
2. SMOLEN JS, LANDEWE R, BREEDVELD FC *et al.*: EULAR recommendations for the management of rheumatoid arthritis with synthetic and biological disease-modifying antirheumatic drugs. *Ann Rheum Dis* 2010; 69: 964-75.
3. COATES LC, MOVERLEY AR, MCPARLAND L *et al.*: Effect of tight control of inflammation in early psoriatic arthritis (TICOPA): a UK multicentre, open-label, randomised controlled trial. *Lancet* 2015; 386: 2489-98.
4. COATES LC, FRANSEN J, HELLIWELL PS: Defining minimal disease activity in psoriatic arthritis: a proposed objective target for treatment. *Ann Rheum Dis* 2010; 69: 48-53.
5. GOSSEC L, SMOLEN JS, RAMIRO S *et al.*: European League Against Rheumatism (EULAR) recommendations for the management of psoriatic arthritis with pharmacological therapies: 2015 update. *Ann Rheum Dis* 2016; 75: 499-510.
6. COATES LC, HELLIWELL PS: Treating to target in psoriatic arthritis: how to implement in clinical practice. *Ann Rheum Dis* 2016; 75: 640-3.
7. GLADMAN DD: Psoriatic arthritis. *Rheum Dis Clin North Am* 1998; 24: 829-44.