

研究成果の刊行に関する一覧表

〔書籍〕

(竹内 勤)

著者氏名	論文タイトル名	書籍全体の編集者名	書籍名	出版社名	出版地	出版年	ページ
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V. 研究成果の刊行物・別冊
(主なもの)

Nobuyuki Miyasaka · Tsutomu Takeuchi · Katsumi Eguchi

Official Japanese guidelines for the use of infliximab for rheumatoid arthritis

Abstract Differences in ethnic backgrounds as well as in medical and socioeconomic status often affect both the efficacy and adverse effects of medications. Recent data suggest an increased risk of opportunistic infections, especially tuberculosis (TB), among rheumatoid arthritis (RA) patients receiving infliximab, a chimeric monoclonal anti-tumor necrosis factor α (TNF- α) antibody. In this regard, the annual incidence of TB is approximately five times higher in Japan than in the United States. Furthermore, since Bacillus Calmette-Guérin vaccination is mandatory in childhood when the skin test for purified protein derivative (PPD) is negative, a high incidence of false-positive PPD skin tests is observed among the Japanese population. In addition, the upper limit of methotrexate dosage to be used for RA is lower in Japan. We have therefore established official guidelines for the proper use of infliximab in Japanese RA patients. In this review, an algorithm for the diagnosis and management of TB in RA is presented in an evidenced-based form.

Key words Guideline · Infliximab · Rheumatoid arthritis (RA) · Tuberculosis (TB) · Tumor necrosis factor α (TNF- α)

Introduction

Rheumatoid arthritis is a chronic inflammatory disease of unknown etiology. Synovial proliferation results in the de-

struction of both cartilage and bone, and tumor necrosis factor α (TNF- α) is thought to play a central role in this process. Infliximab is a human-murine chimeric anti-TNF- α monoclonal antibody with high affinity and specificity.¹ It forms stable complexes with the monomeric and trimeric forms of soluble TNF- α and with the transmembrane forms of TNF- α . Not only neutralizing soluble TNF- α , but also the cytolysis of macrophages and monocytes by binding to transmembrane TNF- α in vitro, might be relevant in its potent anti-inflammatory and immunosuppressive actions. Infliximab, when used with methotrexate (MTX) in rheumatoid arthritis (RA) patients, induces not only significant improvement in the signs and symptoms of RA but also substantial inhibition of progressive joint damage.^{2,3} Infliximab was approved for RA in the United States in 1999.

In spite of its dramatic efficacy against RA, it has been noted that opportunistic infections, especially tuberculosis (TB), can occur among patients treated with infliximab. According to the report by Keane et al.,⁴ the background rate of TB in RA patients is 6.2 cases per 100 000 per year, whereas the estimated rate of TB among RA patients receiving infliximab therapy was 24.4 cases per 100 000 in the United States. Although this report was confirmed by Wolfe et al.,⁵ no cases of TB have occurred in persons with recent purified protein derivative (PPD) skin tests or prophylaxis. These findings reemphasize the importance of TNF- α in host immune response to *Mycobacterium tuberculosis*. In addition, infliximab administration is accompanied with severe acute infusion reactions in approximately 0.5% of patients because of the chimeric structure of the molecule. Given the differences in the medicosocial status of Japan and the high incidence of infusion reactions, the Ministry of Health, Labor, and Welfare of Japan has decided to conduct a special post-marketing survey of the initial 5000 patients treated with infliximab in Japan.

The potential problems of using infliximab in Japanese RA patients are as follows: (1) TB is approximately five times more prevalent in Japan than in the United States, (2) Bacillus Calmette-Guérin (BCG) vaccination given in childhood yields false-positive tests among Japanese so that

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