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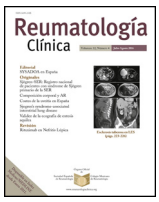

Special Article

Recommendations by the Spanish Rheumatology Society for the Management of Patients Diagnosed With Rheumatoid Arthritis who Cannot Be Treated With Methotrexate☆

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ABSTRACT

To establish a set of recommendations for the management of patients diagnosed with rheumatoid arthritis (RA) who cannot be treated with methotrexate (MTX) due to contraindications, drug toxicity or lack of adherence, and to establish therapeutic strategies more effective and safer in these RA patients. A qualitative analysis of the scientific evidence available to June 2015. The 2-round Delphi technique of consensus was used to collect and establish expert opinion based on the participants' clinical experience when only low quality evidence was available.

A total of 18 recommendations were developed for the management of this patient profile. Fourteen of these recommendations were related to drug safety aspects. Recommendations on contraindication and toxicity of MTX have been updated. The experts recommend the use of biological monotherapy, a preferred treatment option, in patients whose profiles reveal a contraindication, intolerance or circumstances that prevent us against the use of MTX. There is some high-quality scientific evidence that supports contraindication and establishes certain conditions of MTX use in RA patients with specific clinical profiles.

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Documento de Recomendaciones de la Sociedad Española de Reumatología para el manejo clínico del paciente con artritis reumatoide que no puede utilizar metotrexato

Palabras clave:
Artritis reumatoide
Metotrexato

RESUMEN

El objetivo es establecer recomendaciones para el manejo del paciente con artritis reumatoide (AR) que no puede utilizar metotrexato (MTX) por contraindicación, toxicidad o falta de adherencia farmacológica,

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Contraindicación
Toxicidad
Adherencia farmacológica
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y establecer las estrategias terapéuticas más eficaces y seguras. Se realizó un análisis cualitativo de la evidencia científica disponible hasta junio de 2015. Se utilizó un Delphi con un panel de 17 reumatólogos para consolidar la opinión de expertos en aquellas recomendaciones con ausencia o baja calidad científica.

Se elaboraron 18 recomendaciones, y 14 de ellas abordan aspectos de seguridad. Se han actualizado las recomendaciones sobre la contraindicación del MTX y su toxicidad, y se recomienda como una opción terapéutica preferente la utilización de monoterapia biológica en pacientes con contraindicación, intolerancia o circunstancias que desaconsejan el uso de MTX. Existe evidencia científica de buena calidad que contraindica y extrema la utilización de MTX en pacientes con AR con determinados perfiles clínicos.

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Introduction

Rheumatoid arthritis (RA) is a chronic inflammatory disease that affects 0.5% of the Spanish population and, if not treated, causes pain and disability.[1] In 2010, RA was 42nd of the 291 disorders analyzed in the study of the global burden of disease,[2] representing 0.49% (0.36%–0.62%) of the total of years lived with disability. The years lived with disability adjusted for age and the growth in the population between 1990 and 2010 went from 48/100,000 population in 1990 to 55/100,000 population in 2010. In terms of years of life adjusted to disability, in 2010, RA was in 74th place of the ranking, which means 0.19% of the total years of life adjusted to disability.[2] In economic terms, RA also originates a considerable cost to the health system. In 2001, the costs derived from RA in Spain surpassed 2250 million euros, and the calculated direct costs attributable to RA reached 1575 million euros, representing 70% of the total.[3]

The major objective in treating RA patients is to achieve clinical remission or the lowest possible disease activity,[4,5] which has been associated with a better medium-term functional prognosis, although the reduction in the life expectancy of these patients does not seem to have improved throughout the last 20 years.[6] The recommendations of the European League Against Rheumatism (EULAR) for the treatment of RA include the use of methotrexate (MTX) as the first therapeutic option in active patients.[4] Nevertheless, in 10%–36% of the patients who receive MTX, the treatment must be discontinued because of an adverse drug reaction (ADR).[7–10]

Another reason why RA patients cannot take MTX is its contraindication. In the end, the lack of adherence to a treatment regimen, as has been demonstrated in other chronic diseases, originates worse health outcomes and increases the costs of medical care.[11]

This indicates that some patients are limited with regard to treatment with MTX, making it necessary to consider other therapeutic alternatives.

The objective of the present report is to outline recommendations based on scientific evidence, and on the opinion of experts, for the management of patients with RA who cannot receive MTX because of contraindication, toxicity or lack of adherence to the drug regimen, and to establish efficient and safe therapeutic strategies that contribute to achieving a better control of the disease and quality care in these patients.

Materials and Methods

We prepared a qualitative summary of the scientific evidence actually available up to June 2015. We utilized a 2-round Delphi consensus technique to gather and consolidate the opinion of experts on the recommendations in which there was no scientific evidence or the evidence was of low quality.

Literature Search

We searched for literature in the MEDLINE (PubMed) (1950–2015), EMBASE (1980–2015) and Cochrane Library (up to 2015) databases (the latter *via* Wiley Online), for 5 systematic reviews (SR) that required: (1) contraindication for MTX; (2) MTX toxicity; (3) lack of adherence to MTX; (4) therapeutic strategies with synthetic disease-modifying antirheumatic drugs (DMARD) other than MTX in patients who cannot utilize MTX; and (5) therapeutic strategies using biological drugs in patients who cannot take MTX. The literature searches were completed with a manual search of the references cited in articles that the reviewer considered to be of interest. The strategies for the literature searches of the 5 SR can be consulted in Supplementary Material.

The following definitions were used for the SR: (1) contraindication: specific situation in which a drug should not be utilized, as it can be harmful to the patient; (2) drug toxicity: the potential of a drug to produce harmful effects in a person; (3) adverse reaction: the World Health Organization (WHO) defines adverse reactions as a harmful or undesired effect that occurs after the administration of a drug at the doses normally utilized in humans to prevent, diagnose and/or treat a disease; (4) drug intolerance: type B ADR, according to the WHO classification, characterized by not being related to the drug action and to be unexpected; these reactions only develop in susceptible individuals and are due to 2 mechanisms: immunological and pharmacogenetic, and are independent of the dose of the medication and can even develop at subtherapeutic doses; and (5) drug adherence: degree in which the comportment of the patient, with respect to taking the medication, corresponds to the recommendations agreed to with the physician.

Analysis and Synthesis of the Scientific Evidence

We evaluated the quality of the included studies through the critical appraisal of the articles selected for full-text review following a data collection notebook using the templates for critical appraisal provided by the Scottish Intercollegiate Guidelines Network (SIGN).

For the evaluation and synthesis of the scientific evidence, we considered the internal validity of the studies, whether or not there was statistical significance, the accuracy of the outcome and its applicability. The system chosen to classify the scientific evidence is that proposed by SIGN (available in Supplementary Material).

Delphi Consensus

The objective of this consensus technique was to determine the level of agreement among the group of 17 expert rheumatologists with respect to recommendations supported by a low level of scientific evidence (SIGN < 2++) (available in Supplementary Material). Those in which there was a high level of agreement would directly become part of the final set of recommendations.

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