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Editorial

Seminars in Research 2013

Joint Experiences Using Biologics in Rheumatology and Dermatology

We are pleased to present this special supplement of *Drug Development Research*, focusing on the use of biological therapy in the therapeutic areas of rheumatology and dermatology. The supplement has been written by members of the faculty of a Seminar held on September 20–21, 2013 in Avigliano Umbro and facilitated by an unrestricted grant from Pfizer Italia. The contributors are all rheumatologists and dermatologists with substantial experience in the treatment of chronic inflammatory rheumatic and dermatological conditions such as rheumatoid arthritis (RA), psoriasis, psoriatic arthritis (PsA), and spondyloarthropathies (SpA) such as ankylosing spondylitis (AS). These immune-mediated inflammatory diseases (IMIDs) are known to have an overlapping pathology, mediated by cytokines—predominantly tumor necrosis factor (TNF)-α and specific interleukins (ILs)—and involving a wide range of immune cells. Numerous cytokine-targeted therapies such as TNF-α inhibitors, anti-IL agents, and cytokine receptor-targeted therapies have been developed. Many—particularly anti-TNF-α agents—have been shown to be highly effective in the treatment of these disorders and have been approved in a wide range of different IMIDs.

Although biologic agents have revolutionized the management of IMIDs, the long-term use of these agents has now revealed a number of issues that influence their effectiveness and affect their use. We need to be aware of the potential implications of these issues to use biological therapy effectively and safely. To further this objective, this supplement brings together some of the latest research in the area and has been divided into three areas: (i) pharmacogenetics and immunogenicity; (ii) biologics in real life; and (iii) comorbidities of biologic therapies.

The first section contains papers on the potential use of pharmacogenetics to predict response, and examines strategies for identifying patients who will most benefit from these therapies. Papers in this section highlight how pharmacogenomics can be used to identify cell receptors that may be involved in disease pathogenesis—for example, the possible role of the KIR3DL2/B27 dimer in AS pathogenesis [Cauli et al.]—and, thus, uncover potential new therapeutic targets. Other papers examine the immunogenic nature of biologic agents and suggest strategies for assessing immunogenicity [Nencini et al.], evaluating the clinical relevance of antidrug (neutralizing) antibodies [Marinari et al.] and managing patients who become unresponsive to biologic therapy over time as a result of neutralizing antibody formation (Murcada et al.). The impact of thalassemic trait comorbidity in patients with PsA on response to TNF-α blockers is also investigated (Atteno et al.).

In the second section, the included papers provide a wide range of real-world studies of patients with IMIDs treated with biologics, thus demonstrating their application in the clinical setting in a broader range of patients than studied in randomized clinical trials. This section includes papers presenting data from patients with two or more overlapping inflammatory conditions such as psoriasis with gingivitis and periodontitis (Ganzetti et al.). Other papers in this section consider the practicalities of managing IMIDs, such as considerations for use of biologics in patients with chronic infections (Ballanti et al.) and the implications of suspending biologic treatment for surgery to reduce immunosuppression and the potential for infection (Fabiano et al.), identification of patient and clinical factors predicting lack of effect with biologics and discovery and detection of potential biomarkers of response (Giunta et al.; Cacciapaglia et al.), comparison of adherence to and effectiveness of continuous and intermittent biologic regimens (Esposito et al.), presentation of data on long-term persistence of first-line biologic therapy in patients with RA and SpA (Biggioggero & Favalli), and risk of hematological malignancies seen with biological therapy (Conti et al.). Two papers present data from studies evaluating the role of physical exercise in IMIDs, one in RA (Conigliaro et al.), and one investigating adherence to a physical exercise

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program as adjunct to biologic therapy in patients with PsA (Chimenti, Triggianese et al.).

In the final section on comorbidities, papers focus on awareness of common comorbidities seen in patients with IMIDs (De Marco et al.), the effect of biologics on comorbidities—such as the reduction of cardiovascular risk factors with anti-TNF-α therapy in RA patients (Proietti et al.; Cacciapaglia et al.). Other papers consider the potential adverse effects of biological therapy such as antinuclear antibody development (Chimenti et al.), polycystic ovary syndrome (De Simone et al.), hyperuricemia (Gisondi et al.), and the implications of these and other effects on long-term treatment (Spinelli et al.; Piaserico et al.).

We believe that this special supplement of *Drug Development Research* is helpful in highlighting some key issues surrounding the management of IMIDs, and will contribute toward a more effective use of biologics in these complex inflammatory conditions.

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