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Inflectra-Our experience on immunogenicity (Case series)


Biosimilars represent a new tendency in the treatment of many immune-mediated inflammatory diseases, including psoriasis. Regulatory requirements for approval of biosimilars are different from those of originators and rely mostly upon the evidence generated from bioequivalence studies and in particular from RCT, as an important part of it. In our study, case series, we tried to correlate the immunogenicity (measured with ELISA method: Antidrug antibodies and drug level) on eight patients on Inflectra (Infliximab biosimilar), treated more than eight months in our Dermatology Clinic. Our goal was to determine the evolution of the inflammatory markers (ESR, PCR) together with the evolution of PASI, PASI50 and PASI90 on a case series of eight patients for eight months. We were also capable to evaluate the possible correlations between these indices and immunogenicity. We found an interesting fact that from these eight patients, two had sub-therapeutically drug level but not anti-Infliximab antibodies. One of these two patients had also elevated inflammatory markers and the other one has gained more than 10kgs. Peculiar is also the finding that the third patient developed anti-infliximab-antibodies as well as sub-therapeutically trough level of Infliximab. Two months

later, we evaluate the same parameters and we found no anti-infliximab antibodies and therapeutically through level. There is some discussion in the literature regarding the transient anti-drug antibodies and therefore the need to repeat them when positive and mainly when the clinical appearance does not explain the paraclinical findings. Our study concluded that, even on small clinical trial you can find valuable information that can help to tailor the treatment for the patient.

Speaker Biography

Rodica Olteanu is a Dermatologist and Medical Director of Colentina Clinical Hospital, Bucharest, Romania. She has received her PhD on lupus research in 2007, in collaboration with Hamburg University. She is involved in autoimmunity and immunogenicity of biologics and biosimilars and published more than 100 papers in lupus and psoriasis. She is Alumni EADV Club rewarded, winner of many international grants, Member in EADV Project Committee, AAD, GRAPPA, EuSCLE, SRD, ILDS Member and Member in Editorial Board of SRD and LAJPPA. She has completed her educational training by participating at Master Class on Psoriasis- Barcelona, Center for Excellence in Psoriasis-Vienna, Pearls in Lisbon and Bucharest-as Invited Speaker and also at Harvard. She supports the idea of a collaborative work group of specialists in different areas for autoimmune diseases also with patient's participation and she intent to create an Autoimmune Diseases Center in Colentina Hospital.

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