Interpreting safety data from registries

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Ten years ago, when the first biologic agents did get approval to treat patients with rheumatoid arthritis, biologic registers were initiated by the national rheumatologic societies in several European countries. One of their main objectives is to analyze the (long-term) safety of those agents when applied in real life practice.

Several events of interest have been investigated with registries data so far. Among them, results were reported about the risk of tuberculosis, serious bacterial and viral infections and the risk of malignancies.

For serious infections, the analyses of several registers showed an increased risk under treatment with biologic agents compared to treatment with conventional DMARDs only. However, with longer observation time the registers consistently showed a time dependend decrease of serious infections.
In contrast, the reported results about the risk for the recurrence of malignancies are considerably different in their tendency towards a decreased or an increased risk between the British and the German register.

If treatment decisions should be based on the results of register data, one of the questions for the treating physician is “How does this result translate into my practice?” What does an increase in the hazard risk of 40% mean under the specific condition of an individual patient? To which extend should it affect my prescription behavior? And, is it relevant at all? To be able to transfer the results of register data into clinical practice one has on the one hand to know how to translate an increased relative risk in absolute risks or number needed to harm. But in addition, for the interpretation of register data it is as well essential to understand the characteristics of the patient population included in the registers/analyses and to know the pitfalls and possible biases of the underlying observational character of the investigations performed.

The lecture will cover various ways of risk communication as well as the aspects that have to be taken into account when interpreting safety data from registries. Results from biologic registers will be taken as example to show how baseline characteristics of the patients, national guidelines and time varying risk factors may influence the reported safety data.