Considerations on Subgroup Analyses in Clinical Trials☆

Consideraciones sobre los análisis de subgrupos en los ensayos clínicos

As clinicians, we routinely treat patients with drugs whose efficacy is supported by evidence from multicenter clinical trials, some of which include thousands of patients from different parts of the world. When it comes to treating a given patient, however, we need to know whether the beneficial effect described for the average patient will apply to this patient in particular. This can be done by subgroup analysis. Subgroup analysis is a valid tool, but it is not without risk and therefore any conclusions drawn need to be interpreted with caution.

Problems associated with subgroup analyses include loss of statistical power and multiple comparisons. I think that subgroup analyses are justified if they are designed to test a well-formulated hypothesis before the study starts. Inferences made on the basis of a posteriori analyses can be problematic both ethically and methodologically. In this issue, Valenzuela et al. report on the results of a subgroup analysis of the efficacy of ixekizumab in the treatment of psoriasis in the UNCOVER-3 trial in Latin American patients identified by ethnicity. Considering the limited number of patients studied and the difficulty of defining a homogeneous ethnic group for Latin America, their article deserves to be read with care and with consideration of the above-mentioned factors.

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