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Polycythemia Vera: clinical evidence to use Interferon-Alfa in the real world clinical practice

Tiziano BARBUI
FROM Research Foundation, Ospedale Papa Giovanni XXIII, Italy

Abstract

Polycythemia Vera (PV) is a myeloproliferative neoplasm (MPN) characterized by uncontrolled clonal proliferation of multipotent bone marrow progenitors, sustained by acquired genetic mutations in JAK2 genes (JAK2 V617F and exon 12 mutations). In the PROUD-PV/Continuation-PV study, ropeg IFN alfa-2b was effective in inducing haematological responses which continued to increase over time improving responses compared with hydroxyurea. Since there is no evidence that phlebotomy alone is sufficient to steadily maintain hematocrit on target level in low-risk patients, in the Low-PV phase II randomized clinical trial, the efficacy and safety of Ropeg-IFN alfa-2b to maintain the hematocriti on target was launched and results were favorable to this drug. Other trials from MPD-Consortium were performed with other forms of pegilated-IFN alfa, both in front line and as rescue after Hydroxyurea intolerance or resistance. Overall, results suggest that selected patients could achieve substantial hematologic and molecular responses and in some cases the drug can be discontinued opening the way for a potential cure of this disease. To optimize the prescription of this drug as first or second line therapy after Hydroxyurea or Ruxolitinib, a project was launched by the European Leukemia Net (ELN) in January 2021 named Polycythemia Vera Interferon Consensus (POINT-C). Aim of this initiative is to provide clinical indications and management issues of IFN-alpha in clinical real world clinical practice.

For each single outcome (thrombosis, bleeding, evolution into MF or AL, symptoms and quality of life, pregnancy) a specific review of the literature to grade the quality of direct and indirect evidence supporting a net benefit of cytoreductive therapy start, or change, in each subgroup was examined and recommendations were assigned to subgroups of achieving a consensus >=85% or supported by a high-quality evidence for at least one outcome or a moderate evidence for a critical outcome. Weak recommendations will be labelled by a “to be considered” wording. For clinical question concerning the indication and choice of single drugs, all reviewed data will be translated into Patient-Intervention-Comparator-Outcome questions (PICO) and clinical recommendations were produced by a GRADE process. In that question without sufficient evidence, a consensus will be required. During the presentation the results of the POINT-C project will be reported and specific recommendation will be discussed. The major problem of PV patients is represented by major arterial and venous thrombosis vascular complications whose rate is the highest at the time of diagnosis and shortly thereafter (ref x,xx). In the real world clinical practice of contemporary 1500 patients with PV, total major thrombosis rate was 2.62% patients per year, an estimate lower than that reported in the ECLAP trial (4.4% patients per year) but comparable to the rate seen in the recent Cyto-PV study (2.7% patients per year, venous and arterial thrombosis in 1.59% and 1.05% patients per year respectively.

tbarbui@fondazionefrom.it