“The objective of this study was to provide a detailed account of IRs with pegloticase therapy” Baraf et al (2014).

Reference:

Baraf, H.S., Yood, R.A., Ottery, F.D., Sundy, J.S. and Becker, M.A. (2014) Infusion-related reactions with pegloticase, a recombinant uricase for the treatment of chronic gout refractory to conventional therapy. Journal of Clinical Rheumatology. 20(8), p.427-32.

Study identifies infusion-related reactions with pegloticase http://ctt.ec/4C2o7+ @ivteam #ivteam

Click To Tweet

Abstract:

BACKGROUND: In clinical trials of pegloticase, a PEGylated uricase developed for treatment of gout refractory to conventional therapy, infusion-related reactions (IRs) were the second most frequent adverse event reported.

OBJECTIVE: The objective of this study was to provide a detailed account of IRs with pegloticase therapy.

METHODS: Data from 2 replicate, 6-month randomized trials and an open-label extension

study were pooled. Infusions of pegloticase (8 mg) were administered biweekly or monthly; all patients received prophylaxis (antihistamine, acetaminophen, and corticosteroid) and were tested for urate levels prior to each infusion. An IR was defined by protocol as any otherwise unexplained adverse event or cluster of temporally related events occurring during or within 2 hours of infusion.

RESULTS: Infusion-related reactions occurred in 94 (45%) of 208 patients receiving pegloticase; 10 patients reported IRs at first infusion and 84 during subsequent infusions. Chest discomfort (15%), flushing (12%), and dyspnea (11%) were the most common symptoms. Most IRs were rated mild or moderate; 7% were rated severe. All IRs resolved with slowing, interrupting, or stopping the infusion. No patient required blood pressure or ventilatory support. Infusion-related reactions were associated with loss of pegloticase urate-lowering efficacy: 91% of all IRs occurred in patients with preinfusion serum uric acid concentrations (sUA) greater than 6 mg/dL. For patients sustaining preinfusion sUA of less than 6 mg/dL, IRs occurred in fewer than 1 per 100 infusions.

CONCLUSIONS: Phase 3 trial data combined with post hoc analyses demonstrated that knowledge of sUA preceding each pegloticase infusion and cessation of therapy when urate-lowering efficacy is lost provide a means to optimize the safety of pegloticase in clinical practice.

Thank you to our partners for supporting IVTEAM