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Iron chelation therapy with deferasirox in patients with aplastic anemia: a subgroup analysis of 116 patients from the EPIC trial.

The prospective 1-year Evaluation of Patients’ Iron Chelation with Exjade (EPIC) study enrolled a large cohort of 116 patients with aplastic anemia; the present analyses evaluated the efficacy and safety of deferasirox in this patient population. After 1 year, median serum ferritin decreased significantly from 3254 ng/mL at baseline to 1854 ng/mL (P< .001). Decreases occurred in chelation-naive (3229-1520 ng/mL; P< .001, last-observation-carried-forward analysis), and previously chelated (3263-2585 ng/mL; P = .21, last-observation-carried-forward analysis) patients and were reflective of dose adjustments and ongoing iron intake. Baseline labile plasma iron levels were within normal range despite high serum ferritin levels. The most common drug-related adverse events were nausea (22%) and diarrhea (16%). Serum creatinine increases more than 33% above baseline and the upper limit of normal occurred in 29 patients (25%), but there were no progressive increases; concomitant use of cyclosporine had a significant impact on serum creatinine levels. The decrease in mean alanine aminotransferase levels at 1 year correlated significantly with reduction in serum ferritin (r = 0.40, P< .001). Mean absolute neutrophil and platelet counts remained stable during treatment, and there were no drug-related cytopenias. This prospective dataset confirms the efficacy and well characterizes the tolerability profile of deferasirox in a large population of patients with aplastic anemia. This study was registered at www.clinicaltrials.gov as #NCT00171821.