Maintenance intravenous iron in hemodialysis patients to minimize erythropoietin doses: A double-blind, randomized controlled trial (The MAINTAIN IRON Trial)

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Abstract

Background: There is no standard regimen for maintenance iron supplementation in chronic hemodialysis patients. We investigated fixed-appropriate doses of intravenous (IV) iron protocols for maintaining hemoglobin levels and minimizing erythropoiesis-stimulating agents (ESA).

Methods: A double-blind, randomized controlled trial was conducted in hemodialysis patients with ferritin levels of 200-700 ng/dl and transferrin saturation (TSAT) 20-40%. Patients were randomized to receive either 100-mg or 200-mg monthly IV iron. ESA was adjusted monthly to maintain Hb of 10-12 g/dl. The primary endpoint was ESA dose at 12 months. Key secondary endpoints were all-cause mortality, cardiovascular events, absolute iron deficiency anemia (IDA), blood transfusion, adverse events, and iron withholding rate.

Results: Of 79 eligible patients, 40 were in the 100-mg IV iron group and 39 in the 200-mg. Mean monthly ESA dose at month 12 was 35,706 ± 21,637 IU in the 100-mg IV iron group versus 26,382±14,983 IU in the 200-mg group (P = 0.03). Twelve patients (30%) in 100-mg group and four patients (10.5%) in 200-mg one had IDA (P = 0.05). Three patients in each group died (P = 0.9). There were no significant differences in hospitalization, venous access thrombosis, and infection rates in both groups, but slightly higher in the 200-mg cohort. The withholding rate was 25% and 64.1% (P = 0.03).

Conclusion: Monthly 200-mg IV iron doses effectively minimize ESA doses in hemodialysis patients but with a higher withholding rate.

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Keywords: erythropoietin; dialysis; ESKD; ESRD; kidney failure

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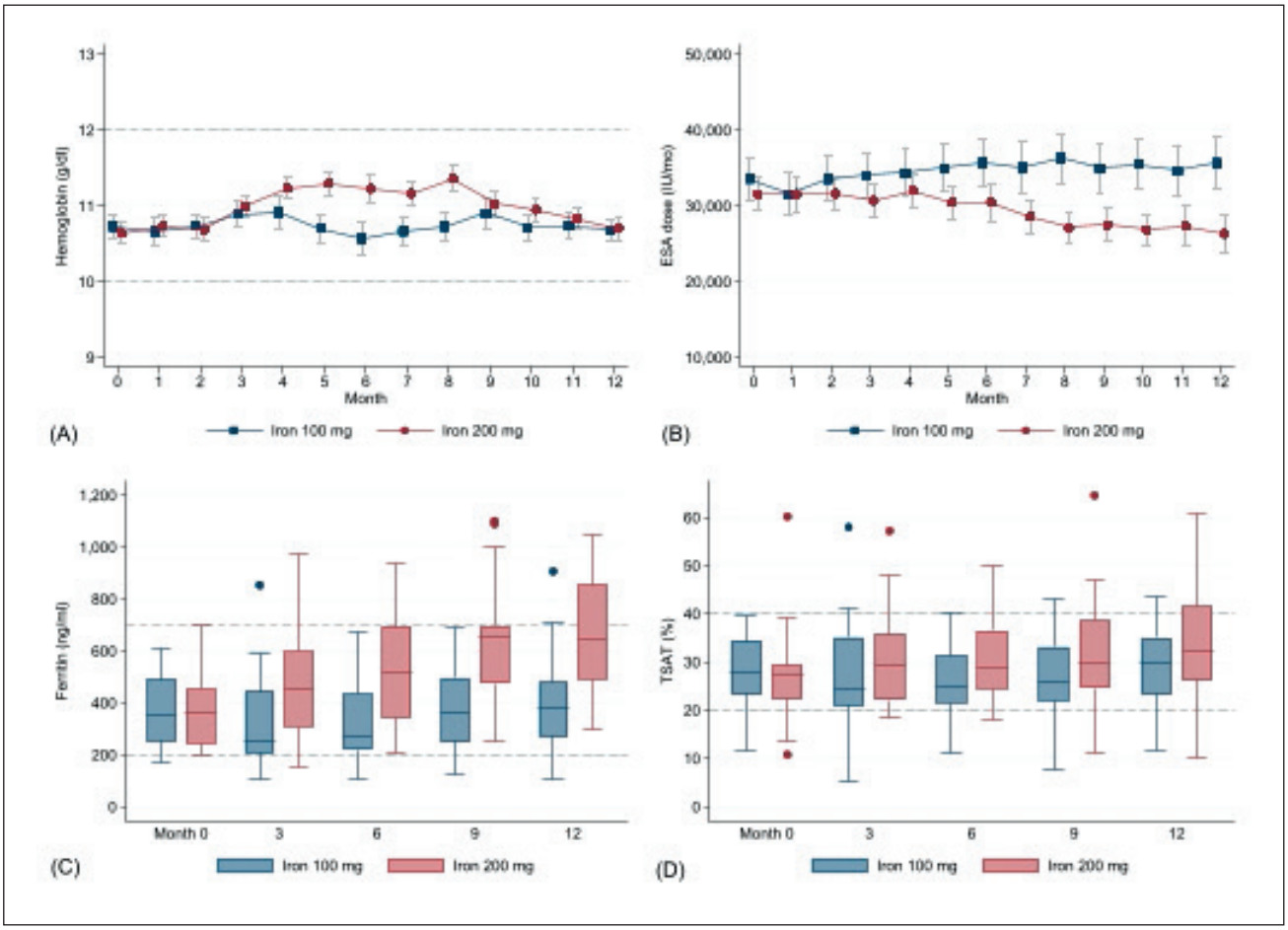
Hemoglobin (g/dl)
Month
(A)
Iron 100 mg
Iron 200 mg
ESA dose (IU/mo)
Month
(B)
Iron 100 mg
Iron 200 mg
Ferritin (ng/ml)
Month 0
3
6
9
12
(C)
Iron 100 mg
Iron 200 mg
TSAT (%)
Month 0
3
6
9
12
(D)
Iron 100 mg
Iron 200 mg

Figure 1