Efficacy of intravenous iron therapy compared to usual treatment in iron deficient adult cyanotic congenital heart disease patients for improvement in clinical outcomes at three months

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**Background:** Iron deficiency is frequent in CCHD patients and is associated with poorer outcomes. Patients with iron deficiency anaemia are treated with oral iron which results in improved clinical outcomes. The use of intravenous iron in CCHD patients is not well studied.

**Purpose:** We aimed to compare effectiveness of intravenous iron with usual care (i.e., no therapy for CCHD patients with iron deficiency without anemia, and oral iron therapy for CCHD patients with iron deficiency anaemia) on 6-minute walk distance (6MWD) after 3 months of treatment, improvement in arterial Haemoglobin saturation, Quality of life, WHO functional class and safety of intravenous Iron.

**Methods:** We enrolled 27 patients of which 13 were randomized to IV iron arm and 14 to usual treatment arm. The mean age (±SD) of enrolled patient was 23.3 (±5.55) years. 24 out of 27 patients (88.9%) were Eisenmenger Syndrome patients, while the other three patients were TOF with pulmonary atresia, DORV with pulmonary atresia and post-Fontan. 6MWD was performed to access functional capacity and WHOQOL-BREF questionnaire was used for assessment of quality of life. All the clinical findings, data and test recordings were repeated after three months.

**Results:** The mean (±SD) haemoglobin (Hb) of patients included in the study was 16.7 (±2.0) g/dl. The Hb levels improved by 0.91 (±0.85) g/dl in patients who received any form of iron therapy (IV or oral iron). Hb improvement was not significantly different between those who received IV or oral iron [IV iron: 1.15 (±0.88) g/dl, Oral iron: 0.59 (±0.79) g/dl; p= 0.12]. The baseline 6MWD was not different in both the arms (p= 0.639). The mean (±SD) 6MW distance covered in IV iron arm and usual treatment arm was 401 (±35.2) m and 408.6 (±46.5) m respectively at baseline, which improved to 425 (±28.7) m and 421.5 (±43.2) m respectively at 3 months follow up. The change in 6MWD in IV iron arm and usual treatment arm was 24 (±22.3) m and 13.1 (±16.4) m respectively. The difference of change in 6MWD between the two arms was non-significant (p= 0.157). There was a significant improvement in WHOQOL-BREF Score Domains 2,3 and 4 and there was a trend towards improvement on Domain 1 score in IV iron arm compared to usual treatment arm. WHO functional class was similar at baseline in both arms (p= 0.534). The change in WHO functional class at follow up was similar in both arms (p= 0.082)

**Conclusion:** This study demonstrated no improvement in clinical outcomes of 6MW distance, arterial hemoglobin saturation and WHO functional class. However, there was significant improvement in quality of life and iv iron was found safe and equally efficacious as oral iron for correcting iron deficiency. Further studies for determining ideal hemoglobin levels and dose of iron in CCHD patients are pertinent.