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Administration of subcutaneous Methoxy polyethylene glycol-epoetin beta (Mircera) in a paediatric cohort; an 8-year retrospective national centre study

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Introduction

Mircera is a pegylated formulation of recombinant epoetin beta which has been used in the management of chronic kidney disease (CKD) associated anaemia in adult patients in Europe and the US since 2007. There is less data demonstrating clinical safety and efficacy in paediatric patients, with only one paediatric phase II trial of 64 patients (DOLPHIN study) identified. We retrospectively reviewed our off-licence use of MIRCERA use in a single national centre, over 8 years.

Methods

Data were collated from electronic case records. All patients receiving Mircera from 2011 onwards were identified. Data collected included lab parameters before therapy, at each dose change, and completion of therapy: haemoglobin, parathormone (PTH), ferritin, haematinics. Demographics included gender, CKD stage and aetiology, reason for discontinuation of therapy, adverse effects. Efficacy of Mircera was defined as Hb levels≥100g/dL. An upper limit of Hb≥ 130 g/dL was applied, with ongoing administration at the same dose considered over-treatment. Primary outcomes were safety (number of adverse events), efficacy (time to target Hb), dose ranges and duration of treatment. Secondary outcomes included association of efficacy with hyperparathyroidism (PTH>60pg/ml), CKD stage, glomerular/non-glomerular aetiology, inflammation, medication, dialysis, transplant and iron status.

Results

77 patients were identified. Two patients were excluded as weight and Haemoglobin (Hb) values were unavailable, leaving 75 patients for analysis. 44 patients (59.5%) had Hb≥100g/dL before treatment, 55 (73%) post-treatment. A total of 243 doses of Mircera were administered and had Hb values available. 161 doses (66.3%) resulted in a Hb≥100g/dL. The mean initial dose was 2.2mcg/kg. Doses of 1-2 microgram/kg resulted in 70% of Hb values being ≥100g/dL. Higher doses (≥4mcg/kg) resulted in 79% of Hb values being ≥100g/dL but 11.9% were a Hb≥130g/dL. Dosing frequency ranged from 1 to 8 weeks, with the majority (72%) of doses administered 4 weekly.

Mircera was safe in paediatric patients. No patients discontinued therapy due to adverse events. Mean treatment duration was 20.5 months, with approximately 6 months treatment required to achieve stable (≥70% Hb values) consecutive Hb values.

Hyperparathyroidism was associated with Mircera hypo-responsiveness. 28 of 230 (12.2%) documented PTH levels were >60pg/mlof which 18/28 (64.3%) were associated with Hb<100g/dL. 202 of 230 (87.8%) documented PTH levels were <60pg/ml, of which 55/202 (27.2%) had Hb<100g/dL. Serum ferritin≥500ng/mL was also associated with reduced treatment efficacy. At baseline 11.7% of ferritin was ≥500ng/mL of which 68% had Hb<100g/dL. Similarly, post-treatment 14.3% of ferritin was ≥500ng/mL of

which 64.3% had Hb<100g/dL. Mircera was effective in all CKD stages, except CKD 3. Medication, aetiology, dialysis, transplant and iron status did not affect MIRCERA efficacy.

Conclusion

Mircera is safe and effective in children aged 2-18 years old. Fewer doses were associated with higher Hb in patients with PTH>60pg/mL, or ferritin >500ng/mL.