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Cinacalcet: an audit of prescribing practices and clinical effectiveness. Is it time for change?

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Background

End-stage renal disease (ESRD) results in hyperphosphatemia and hypocalcaemia from impaired renal phosphate clearance and reduced synthesis of 1,25-dihydroxyvitaminD. As a result, Secondary hyperparathyroidism (SHPT) occurs in almost all patients with ESRD and is associated with cardiovascular and soft tissue calcification – major contributors to morbidity and mortality.

Routine management of SHPT includes dietary phosphate advice, binders and vitamin D analogues. Surgical parathyroidectomy or cinacalcet is reserved for those refractory to standard treatment.

Cinacalcet is a high-cost drug, directly commissioned by NHS England. To ensure the use of cinacalcet remains clinically and cost effective, the National Institute for Health and Care Excellence (NICE) set prescribing criteria for the initiation and ongoing use. In a climate of increasing fiscal pressures, it is anticipated that Trusts will soon be asked to provide evidence that cinacalcet prescribing meets NICE recommendations.

Aim

To investigate whether patients are being prescribed Cinacalcet according to NICE guidance

Objectives

1. Assess if patients have a serum PTH >85pmol/L and normal-high serum calcium (≥2.05mmol/L) on commencement of Cinacalcet
2. Assess if ≥30% PTH reduction is achieved at 4 months

Method

A clinical audit was undertaken of all patients currently prescribed Cinacalcet on our Trust's renal database, PROTON (n=69). Of these 15 were excluded for the following reasons: 1. Cinacalcet being commenced by another Trust 2. <4 months from initiation 3. Insufficient data.

Retrospective PTH, calcium and phosphate results were recorded at initiation of cinacalcet, and at 4 and 12 months.

Results

Only 39% (n=21) had a PTH >85pmol/L on commencement of cinacalcet whereas 100% of patients (n=54) had a normal-high calcium; median 2.52mmol/L (2.13-3.00). Of the 45 patients that had PTH levels checked at 4 months, 42% (n=19) achieved a ≥30% reduction; median 20% (-228% to 89%). At 12 months 75% had

achieved ≥30% reduction; median 49% (-98 to 100%). 41% of patients (n=22) had their cinacalcet dose increased; the median number of days until the first dose titration was 119 (31-321).

Discussion

All patients met the calcium criteria at initiation of cinacalcet, but the majority had a PTH below 85pmol/L. Scrutiny of the data and clinical letters revealed hypercalcaemia as the indication for initiation in patients with a PTH level within target range.

Our data also showed occurrences of a PTH rise during cinacalcet treatment, suggesting either non-adherence or sub-therapeutic dosing. In addition, dose titrations did not meet the 2-4 weekly recommendations set out in the British National Formulary; this is likely to have had an impact on effectiveness.

Limitations of the audit include timeliness of cincalcet being added to PROTON; time delays between prescribing and receiving; possible non-adherence; and supply problems.

There may be clinical rationale for prescribing cinacalcet outside NICE criteria; however, with increasing financial constraints there is justification for a critical review of both prescribing and monitoring processes. It is imperative to ensure clinical and economical effectiveness through regular monitoring, timely dose titration, and encouragement of adherence. In an already stretched nephrology service this may warrant the need for a designated cinacalcet/mineral bone clinic.