Basildon and Thurrock University Hospitals NHS
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RESPONSE TO CINACALCET THERAPY IN HAEMODIALYSIS PATIENTS; ASSESSING THE SUITABILITY OF NICE GUIDANCE

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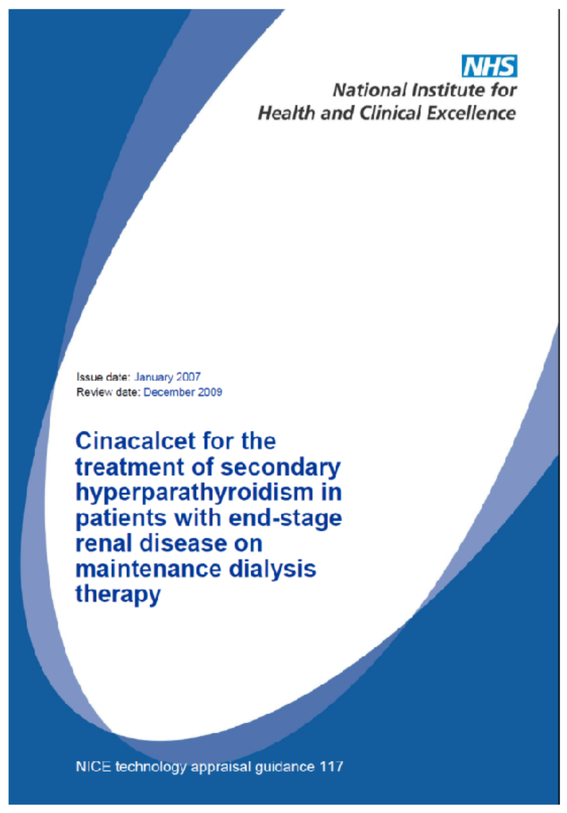


Introduction

Secondary hyperparathyroidism is a source of significant morbidity for haemodialysis patients. NICE guidelines recommend cinacalcet for those with high parathyroid levels despite standard treatment and are not suitable for parathyroidectomy.[1] While effective at reducing parathyroid levels, cinacalcet treatment is expensive and a recent multi-centre trial hasn't shown mortality benefit with its use.[2] In light of the results from the EVOLVE study we set out to analyse adherence to NICE guidelines and their suitability and relevance to haemodialysis patients in a U.K. setting.

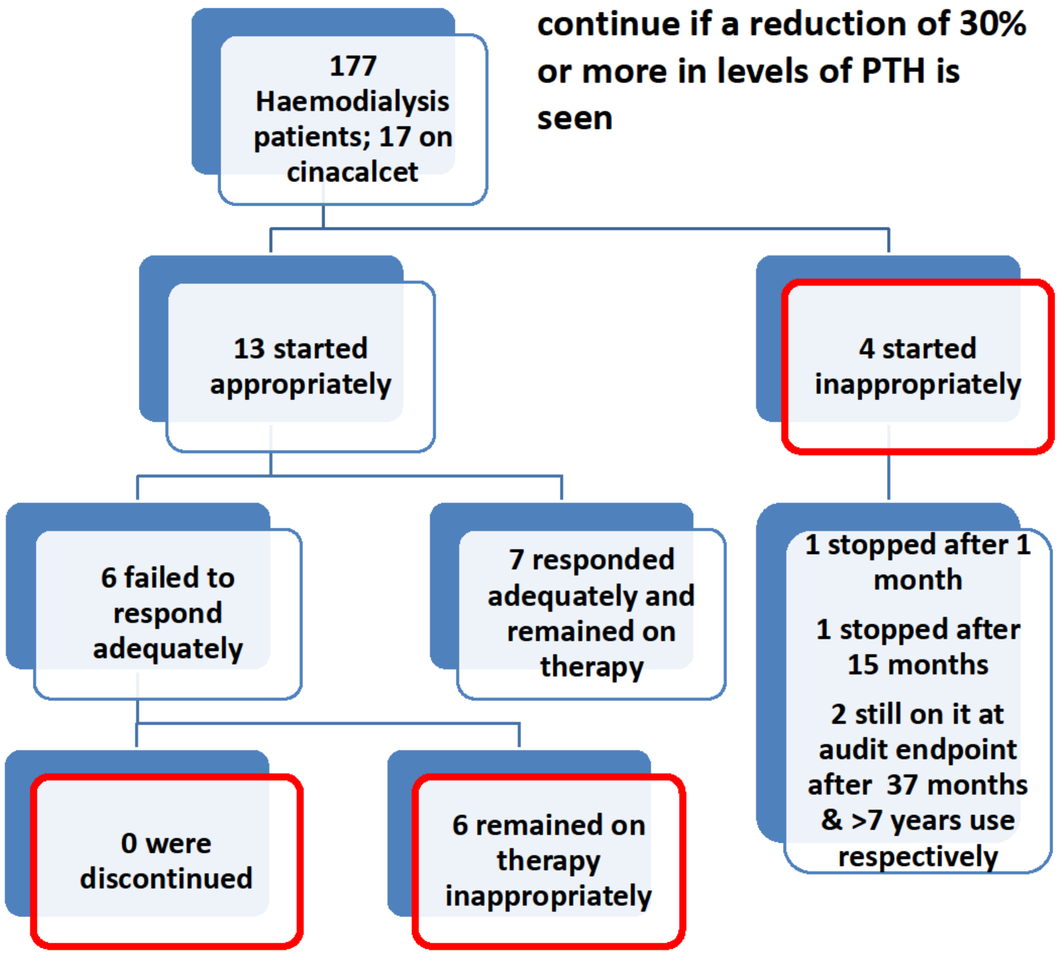
Methods

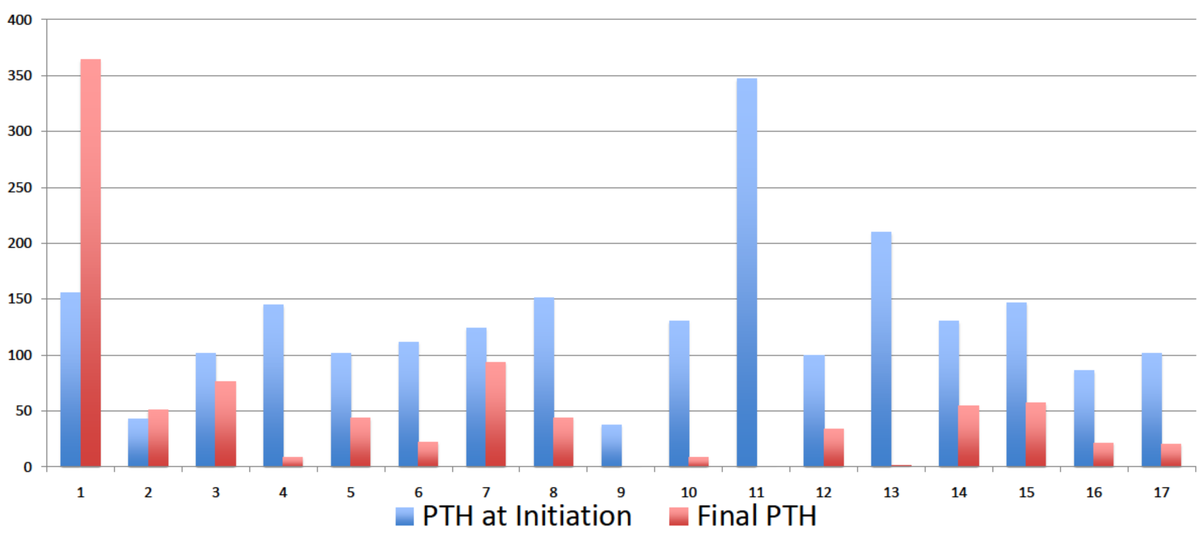
This was a retrospective data analysis of all haemodialysis patients on cinacalcet at any time from 01/11/2012 to 31/10/2013. Our usual practice is to review medications either during monthly QA blood meetings or at clinic visits. We analysed all PTH, calcium, and phosphate levels that were taken from the initiation of their cinacalcet therapy until their cessation or the chronological end point of our study. Data was analysed in the context of NICE's stipulations for initiation and continuation of therapy [PTH levels should be >85pmol/L and show a 30% reduction at 4 months]. Expenditure on cinacalcet was calculated, and compared to expenditure if NICE guidance was rigidly followed.

- **PTH levels > 85pmol/L**
  - **Refractory to standard therapy**
  - **Normal or high adjusted calcium**
  - **Where parathyroidectomy is contraindicated.**
- **Treatment should only continue if a reduction of 30% or more in levels of PTH is seen**

Results

There were 210 dialysis patients, of which 177 were haemodialysis. 17 of these received cinacalcet therapy (9 male, 8 female; age 25 to 79 years, mean 59.8). At 4 months the mean reduction in PTH was 29.8%, but at 8 months it was 51.8%. Mean time to become therapeutic was 25.2 weeks. Only 1 patient stayed consistently therapeutic on cinacalcet. All others rose above the 70% cut off at least once. All bar 4 patients climbed above their PTH baseline whilst on cinacalcet. 10 patients failed to reach therapeutic targets by 4 months but treatment continued. 9 of these were therapeutic at 12 months. One patient failed to ever become therapeutic.





Graph showing PTH levels at initiation and at study end point for each patient.

Prior to study 4 patients had undergone subtotal surgical parathyroidectomy. 2 others underwent it and 1 converted to total during analysis. Of the rest, 3 were awaiting transplant (thus suitable for surgery) and 8 did not have a documented decision regarding suitability for surgical parathyroidectomy. With more strict adherence to NICE there was a potential saving of £104,000 in total.

Conclusions

The results show that in a our setting cinacalcet was effective at reducing parathyroid levels, however the time taken to achieve this occurred outside of NICE guidance for the majority (10 out of 17 failed to have a 30% reduction at 4 months). More rigorous follow up and aggressive dose escalation of cinacalcet might produce more effective suppression of PTH levels in our patients. However this work gives insight into the realities of cinacalcet in a "real world" setting (which we believe is not dissimilar to the practice of many renal units in the U.K.). Even with appropriate dose escalation of cinacalcet a large randomized controlled trial has failed to prove it has a mortality benefit over placebo (EVOLVE)[2]. In light of the findings of EVOLVE and our data showing the realities of cinacalcet prescribing one would have to question the value of cinacalcet in a setting such as ours. The other consideration is that, given the relative young age of the patients in this study (mean age 60), whether we should be more rigorously pursuing a surgical option for patients on cinacalcet [4,5].

References:
1) Cinacalcet for the treatment of secondary hyperparathyroidism in patients with end-stage renal disease on maintenance dialysis therapy. NICE Technology Appraisal Guidance TA-117. 2007 January.
2) Effect of Cinacalcet on Cardiovascular Disease in Patients Undergoing Dialysis; *The EVOLVE Trial Investigators;* N Engl J Med. 2012 December; 367:2482-2494.
3) European Renal Association-European Dialysis and Transplant Association (ERA-EDTA) 51st Congress: Abstract TO013
4) Parathyroidectomy and survival among Japanese hemodialysis patients with secondary hyperparathyroidism. Komaba H, Taniguchi M, et al. Kidney Int. 2015 March. doi: 10.1038/ki.2015.72. [Epub ahead of print]
5) Parathyroidectomy versus cinacalcet hydrochloride-based medical therapy in the management of hyperparathyroidism in ESRD: a cost utility analysis. *Narayan R, Perkins RM, et al.* Am J Kidney Dis. 2007 Jun; 49(6):801-13.5

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