

The role of Etelcalcetide in the management of CKD-MBD in hemodialysis patients.

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In the management of CKD MBD, three key laboratory data to address are calcium, phosphorus and PTH. The different classes of drugs used to manage CKD MBD are phosphate binders, active vitamin D and calcimimetics. These drugs have differential effects on the three key lab data. Phosphate binders lower phosphorus, decrease PTH in the process as well and will either increase or have a neutral effect on calcium depending on the binder. Active vitamin D lowers PTH but at the same time increases phosphorus and calcium. Calcimimetics lower all three key lab parameters. Per the new KDIGO guidelines, calcimimetics can be used as first line agent for managing CKD MBD, and all three key labs should be taken into account while addressing CKD MBD and trends should be looked. We also should try to avoid hypercalcemia. Despite having all these medications available, we are still doing quite poorly in getting our patients to goal with respect to the three key labs. The newly approved IV calcimimetic etelcalcetide has unique pharmacology. It is an octapeptide with seven of the eight amino acids being dextroisomers. It has some potential advantages over its oral counterpart cinacalcet. Besides being given IV, it has a longer half-life and also appears to be more efficacious with lesser GI adverse events. This is definitely an advancement for patients who either failed cinacalcet or were intolerant of it. These class of drugs have the potential to avoid parathyroidectomy. Being given IV, compliance is 100 percent as long as patient shows up for dialysis. We also have safety and efficacy data for up to 78 weeks. Hypocalcemia is the major adverse event and is mechanism based and dose dependent and is expected being a calcimimetic. Hypocalcemia is manageable and only one percent patient discontinued the drug in Phase III registrational trials due to hypocalcemia with no deaths reported. PTH on an average dropped by 50 percent from the base line with 5-10 percent drop seen in calcium and phosphorous. Overall, these results indicate that long-term administration of etelcalcetide exhibits a reasonable safety profile with sustained reductions in PTH, Ca and P.