

Bone Histology Validation of the Scantibodies 1-84 PTH (CAP) Assay and the 1-84 PTH/Large C Terminal PTH Fragments Ratio

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Based on bone histology, Faugere et al., have determined the utility of various biochemical markers to predict bone turnover and found the ranking—from best to worst—as follows: 1-84 PTH/C terminal fragment ratio, 1-84 PTH (CAP), bone alkaline phosphatase, intact PTH and osteocalcin (Kidney Int. 2001; 60:1460-1468). We found the same ranking with the exception that intact PTH was better than bone alkaline phosphatase. A diagnostic guide that incorporates the top 2 markers (ratio and 1-84 PTH) should have more diagnostic value than the ratio alone. The alarming rise in the incidence of ABD (adynamic bone disease)—and that misidentification could result in oversuppression, worsening patients' condition—underscores the need for a routine method to identify ABD. Thus, it is desirable to know the cutoff, with bone histology, for the same 1-84 PTH (CAP) assay utilized in the Faugere study.

25 routine dialysis pts, representative of our clinic, were enrolled with informed consent in this bone biopsy study. Following standard double tetracycline labeling, a vertical iliac sample was taken. Specimens were processed to undecalcified section and stained for histometrical evaluation. Low turnover bone was defined as $BFR/BS < 10 \text{ mcm}^3/\text{mcm}^2/\text{yr}$ (Calcif Tissue Int. 1988; 42:13-17). Of the 25 pts, 16 had low bone turnover, and 9 had either normal or high bone turnover. For the pts with low bone turnover, all had a CAP assay value $< 90 \text{ pg/mL}$, except for 5 pts. For the 9 pts with either normal or high bone turnover, all had a CAP assay value $> 90 \text{ pg/mL}$. Youden index revealed a sharp rise with a peak of 90 pg/mL , and a flat segment up to 170 pg/mL . Thus, bone histology indicates the CAP assay range of $90\text{-}170 \text{ pg/mL}$ as normal bone turnover.

According to our findings, the ratio cutoff is 1.4 for dialysis pts. That is, a ratio of < 1.4 for dialysis pts we studied indicates low turnover bone. Coupling the ratio and CAP cutoff values into a single diagnostic guide to identify low turnover bone leads to 2 practical questions: 1) Is the CAP value $< 90 \text{ pg/mL}$; and 2) Is the ratio value < 1.4 ? This guide should be further studied with histology to identify ABD.

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