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Letter to the Editor

Comparison of Liaison N-tact PTH (Diasorin) and N-tact PTH SP IRMA (Diasorin) in hemodialyzed patients

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In a recent report, Souberbielle et al. (1) showed good correlation ($r=0.92$; $p<0.001$) between intact parathyroid hormone (PTH) concentrations measured with the Allegro® assay (Nichols Institute, San Juan Capistrano, CA, USA) and the Liaison® assay (Diasorin, Saluggia, Italy) in 167 hemodialyzed patients. Using the equation y (Liaison) = 0.79 × (Allegro) + 50.3 (ng/L), they calculated equivalent values between the assays and found that the 150–300 ng/L PTH levels recommended by the guidelines for management of renal osteodystrophy (2) might equate to 169–288 ng/L for the Liaison assay. A similar study was performed in our hospital on 80 hemodialyzed patients: we compared measurement of intact PTH using the new Liaison assay and the N-tact PTH immunoradiometric assay (IRMA; Diasorin, Saluggia, Italy) routinely used in our laboratory. Although the correlation was good ($r=0.993$; $p<0.0001$), the regression equation was y (Liaison) = 1.21 × (IRMA) + 28.29 (ng/L), and a Bland-Altman plot showed a mean difference of 68 ng/L between the two tests (Figure 1). When differences were plotted as percentages of the average, the mean difference was 33.8% for the whole group, with interquartile differences of 32.4%, 40.9%, 36.8% and 25.1%, respectively, for Q1–Q4. The K/DOQI Clinical Practice Guidelines for Bone Metabolism and Disease in Chronic Kidney Disease (2) suggest a therapeutic approach to bone disease in chronic kidney disease based on its specific type and on targets of intact PTH that should range between 150 and 300 ng/L. However, these guidelines, based on evidence derived from the Nichols Allegro manual IRMA intact PTH assay, do not indicate that the PTH targets are specific for this method. In our study, 22 patients were within the range 150–300 ng/L as measured using the N-tact Diasorin IRMA. For this subgroup, the Bland-Altman plot showed a mean difference of 37%, and the 90% confidence interval range found by the Liaison assay for this population was 204–409 ng/L. When the Liaison method was validated, we found a detection limit of 1.81 ng/L, and repeatability of 3.3% and 2% at 26 and 262 ng/L, and reproducibility of 7% and 5% at 71 and 618 ng/L, respectively. An enrichment test performed with hPTH-(1-34) (Ref. H-1370, Bachem, Bubendorf, Switzerland) showed a mean recovery of 88%. PTH-(7-84) affected both tests in the same way, with a mean cross-reaction of 46% for the IRMA and 53% for the Liaison assay. We established reference values for the Liaison assay in a population with plasma calcium and creatinine within the normal ranges and 25-hydroxy vitamin D > 50 nmol/L. In this limited population (100 subjects), the upper limit was 88 ng/L, slightly higher than the limit proposed by Diasorin (82 ng/L), but much higher than that proposed by Souberbielle et al. (51 ng/L) (1). We have no clear explanation for these discrepancies. Recently, Holmes et al. (3) underlined the importance of preanalytical influences on the determination of intact PTH. For our part, we use 5-mL Terumo (Haasrode, Belgium) Venosafe™ plastic tubes containing gel and clot activator. Samples were drawn directly after the end of the dialysis and immediately brought to the laboratory, where they were immediately centrifuged and kept at +4°C. If assays were not performed on the day of the sampling, sera were directly frozen at −20°C, because when we investigated the stability of intact PTH in our laboratory, we concluded that PTH in serum is stable for only 24 hours at +4°C and for up to 1 month

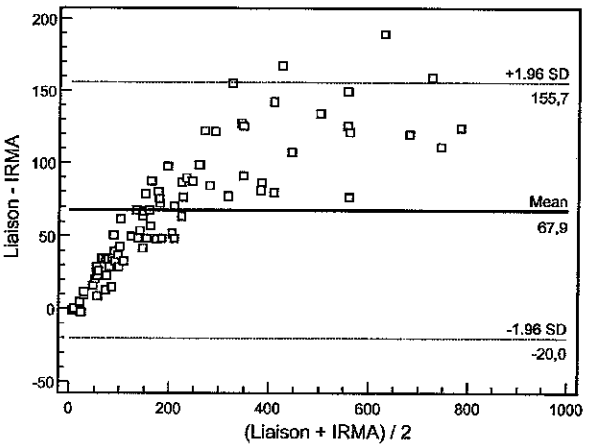

Figure 1 Bland-Altman plot for PTH results (ng/L) obtained in 80 hemodialyzed patients with the N-tact PTH IRMA and Liaison assays.

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at −20°C. Moreover, in our daily practice, two quality controls are performed at the beginning and end of each integral. We noted that from time to time towards the end, the Liaison kits were not as reliable as they were at the beginning. In conclusion, great care is required when changing routine methodology from IRMA to chemiluminescence for the determination of intact PTH, especially when tests are performed in an end-stage renal disease population. Clinicians should be aware that this change significantly increases the absolute IRMA values. As new IRMA and chemiluminescence techniques become available for the determination of PTH in its "intact" or "whole" form, clinical laboratories should indicate on their reports which methodology is used for such determinations.

References

1. Souberbielle JC, Fayol V, Sault C, Lawson-Body E, Kahan A, Cormier C. Assay-specific decision limits for two new automated parathyroid hormone and 25-hydroxyvitamin D assays. Clin Chem 2005;51:395–400.
2. K/DOKI guidelines for the management of renal osteodystrophy. Am J Kidney Dis 2003;42(Suppl 3):S1–201.
3. Holmes DT, Levin A, Forer B, Rosenberg F. Preanalytical influences on DPC IMMULITE 2000 Intact PTH Assays of plasma and serum from dialysis patients. Clin Chem 2005;51:915–7.