ANALYTICAL AND CLINICAL VALIDATION OF A NEW IMMUNOENZYMATIC METHOD FOR THE MEASUREMENT OF CANINE PARATHYROID HORMONE

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Background: Renal hyperparathyroidism (RHPT) is frequent in dogs affected with Chronic Kidney Disease (CKD), with an increasing prevalence according to the severity of disease. The measurement of the parathyroid hormone (PTH) allows to establish adequate treatments, verify their effectiveness and follow the disease progression. However, due to lack of available methods and costs, it is not routinely performed.

Objective: The aims of the study were: the analytical validation of a new immunoenzymatic method for the measurement of PTH validated in humans; the correlation of the obtained results with renal status, expressed as IRIS stage.

Methods: Twenty-eight dog undergoing physical examination, blood works and urinalysis for diagnostics purposes were included in the study. All dogs were classified according to the International Renal Interest Society (IRIS) CKD staging system. The measurement of PTH was performed after routine analyses using an automated analyzer (AIA 360®) and an enzyme immunoassay system (ST AIA-PACK® Intact PTH, Tosoh Bioscience, Tessenderlo, Belgium). The analytical validation was performed on pooled sera with different PTH concentrations. Intra-assay and inter-assay precision, accuracy by linearity under dilution (LUD) and spike recovery test (SRT) and storage stability (20°C, 4°C, -20°C) were assessed. The clinical validation was obtained comparing PTH values with serum creatinine (sCr), phosphorus (P) and IRIS stage. JMP 14 (SAS Inc, Cary, USA) has been used for statistical analysis.

Results: Intra-assay coefficients of variation (CVs) were 6.59%, 2.66% and 5.97% in low, medium and high PTH pool respectively. Inter-assay CVs were 3.42%, 2.51% and 1.83% respectively in the three pools. LUD (r^2=0.99, p<0,0001) and SRT (r^2=1,00, p<0,0001) showed an optimal agreement between observed and expected results. A limit of detection of about 1 pg/ml was obtained. The evaluation of storage stability showed CVs exceeding 10% after 24 hours at room temperature both in high and low PTH pool. At 4°C the CV remained below 10% after 72 hours. At freezing temperature CV was always less than 6%. A statistically significant positive correlation (p<0.01) was found between PTH and sCr, P and IRIS stage.

Conclusion: ST AIA-PACK® is a precise and accurate method to detect PTH in canine serum. The results obtained showed good agreement with the renal status of the dogs enrolled. This study shows promising results for the use of this method in the routinely measurement of PTH in dogs affected with CKD.