

Diagnostic Value of Serum κ/λ Free Light Chain Assay for Monoclonal Gammopathy in Renal Insufficiency Patients

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Background: Patients with monoclonal gammopathy (MG) frequently showed reduced renal function, hence, the differential diagnosis should include MG in these patients. Serum free light chain (sFLC) κ/λ ratio (rFLC, reference: 0.26–1.65) was generally used as a screening test for the presence of plasma cell disorder (PCD). However, in patients with renal impairment, the amounts of κ FLC cleared by the kidneys progressively falls relative to λ and this manifestation leads to false-positive results. In these days, an extended renal reference range of rFLC (0.37–3.17) was proposed, which seems to have more validated in clinical setting. In this study, we performed sFLC testing in combination with serum (s-PE), urine protein electrophoresis (u-PE), and pathologic diagnosis in patients with renal impairment to determine the diagnostic usefulness of sFLC testing in these patients.

Methods: Patients who visited the nephrologists due to renal insufficiency were enrolled (n=299). PE and sFLC quantification were performed in order to find the causes of renal insufficiency. BM analysis was performed for the patients who showed abnormal PE, abnormal sFLC quantification or rFLC, hypergammaglobulinemia or abnormal CBC results.

Results: Median serum Cr and eGFR were 2.0 mg/dL (ranges; 1.4–21.8) and 29 mL/min/1.73m² (2–60) (54.2% CKD, 45.8% AKI). Of total 299 patients, 28.1% were diagnosed as PCD (89.3% MM, 5.9% monoclonal gammopathies of undetermined significance, 1.2% plasmacytoma, and 3.6% systemic amyloidosis without evidence of clonal BM plasma cell). The renal range of rFLC increased sensitivity (95.2% vs. 90.5%) and specificity (97.2% vs. 93.9%) for diagnosis of PCD compared to those with conventional one. The area under the ROC curve in renal ranges increased from 0.96 (95% CI: 0.93–0.99) to 0.92 (0.88–0.96) in conventional one. rFLC results according to the renal reference range were highly sensitive to find the patients with PCD compared to those of PE (sensitivity: s-PE 90.7%, u-PE 74.7%). In twenty patients with light chain multiple myeloma (LCMM), rFLC assessment (100% positive) showed higher accuracy in diagnosis compared than s- and u-PE (78.9% and 80.0%). Renal insufficiency stages and undergoing hemodialysis did not significantly affect these results.

Conclusion: We demonstrated the diagnostic value of rFLC in renal insufficient patients suspected of MG. sFLC assessment is a superior tool in the assessment for PCD, especially for LCMM

Key Words: light chains, Plasma cell neoplasms, Renal insufficiency