

Eur. J. Clin. Chem. Clin. Biochem.
Vol. 31, 1993, pp. 683–687

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Berlin · New York

Rapid Screening of Low Molecular Mass Proteinuria: Evaluation of the First Immunochemical Test Strip for the Detection of α_1 -Microglobulin in Urine

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(Received May 24/July 12, 1993)

Summary: A new semiquantitative immunochemical test strip for urinary α_1 -microglobulin, a marker protein for tubular proteinuria, was assessed. This test strip has four colour zones, reflecting α_1 -microglobulin concentrations of ca. 10, 25, 50, and 80 mg/l. α_1 -Microglobulin concentrations were measured by means of the test strip and an immunonephelometric method in 330 samples collected as the second voided morning urine. The reading time of the test strip must be strictly observed. Reading one minute earlier or later than the 5 min stated in the instructions led to misclassification of over 70% of the results. Correlation between both methods was highly significant, with a *Spearman* rank correlation coefficient of $r_s = 0.84$ ($P < 0.001$). There was a partial overlap of the test strip results in different concentration ranges. An elevation of α_1 -microglobulin was defined as > 25 mg/l, calculated as the upper limit of the central 95% interval of α_1 -microglobulin concentration in urine samples measured in a previous study of 304 healthy adults. Using this definition of α_1 -microglobulin elevation, a sensitivity of 97.5%, specificity of 73.6%, a false-positive rate of 16.6%, and a false-negative rate of 0.9% of the test strip results were obtained. A fraction of 82.4% of the 330 samples investigated was correctly classified as having increased α_1 -microglobulin concentration or not. Methodical improvements of the test strip are necessary to reduce overlapping results, in order to make the test suitable for screening purposes.

Introduction

Since the onset of renal tubular damage is often not preceded by other warning signs of renal dysfunction, it has been suggested that the measurement of low molecular mass proteins in urine should be used as an indicator of renal dysfunction (1, 2). Low molecular mass proteins such as β_2 -microglobulin, retinol binding protein, ribonuclease, and α_1 -microglobulin have been recommended as potential markers for detecting this type of proteinuria, which is known as tubular or low molecular mass proteinuria (3). Several authors have reported the advantages of α_1 -microglobulin in comparison with the conventional marker β_2 -microglobulin (4–8). However, current methods like enzyme immunoassays, single radial immunodif-

fusion, and nephelometric techniques described for laboratory measurement of this protein are not suitable as screening procedures (6). Simple approaches, such as the Micral-Test strip for microalbuminuria (9–11), which is easy to apply and yields quick results, would be useful.

The objective of this study was to evaluate a recently developed immunochemical test strip for α_1 -microglobulin in urine as a means of detecting low molecular mass proteinuria. We assessed the possible discrimination power of this test for normal and increased values of α_1 -microglobulin in urine by comparing semiquantitative test strip with quantitative immunonephelometric results for different reference intervals of this protein.