

MICROALBUMINURIA ESTIMATION BY A NEW DIP STICK METHOD
—COMPARISON WITH RADIOIMMUNOASSAY

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SUMMARY

The usefulness of a dipstick method for estimation of microalbuminuria (MA), the Micral test (Boehringer Mannheim, West Germany) was evaluated by comparing the results with those obtained by a radioimmunoassay (RIA). The sensitivity of Micral test was 89% and its specificity was 99%. The test is performed in about 6 minutes and the test principle is immunochemical in nature. It is a reliable and rapid procedure for semiquantitative estimation of microalbuminuria.

INTRODUCTION

Presence of microalbuminuria (MA) defined as an albumin excretion ≥ 20 to 200 mg/l (or 30 to 300 mg/day) is a strong predictor of clinical nephropathy¹. Detection of microalbuminuria is important because at this stage therapeutic intervention may help to reverse. Detection of MA in any form of diabetes is therefore of great significance. At present quantitative estimation of MA is possible either by nephelometry or by radioimmunoassay (RIA), both of which require special laboratory facilities and personnel and the results may not be available immediately in the out patient clinic. The Micral test is a new rapid semiquantitative dip stick test introduced by Boehringer Mannheim (West Germany). This study was designed to test the usefulness of the Micral test in comparison with a standard RIA procedure.

MATERIAL AND METHODS

Random urine samples collected from consecutive diabetic patients with ≥ 5 year dura-

tion of diabetes were tested. If the proteinuria exceeded ≥ 150 mg/l by the sulphosalicylic acid test, the samples were excluded. A total of 120 samples were tested both by the Micral test and the RIA for albumin. The Micral test was carried out at the room temperature with 30 minutes of the sample collection. An aliquot of urine was kept frozen at -20°C for the RIA procedure. The microalbuminuria kit of Pharmacia, Uppsala was used. The sensitivity of the kit was 0.4 ng/ml and the measuring range was 0.8 to 8 ng/ml. Intra and interassay coefficients of variations were $< 5\%$ and $< 7\%$ respectively. Urine sample was diluted 1:2 when the albumin excretion was above 80 mg/l.

Test principle of Micral test

Human albumin is semiquantitatively estimated by an immunochemical procedure^{2,3}. The test strip is dipped into the urine just below the zone coloured blue, for 5 sec. without touching the sides of the container. The strip is withdrawn and kept flat on a non-absorbant surface. After exactly 5 minutes the colour on the reaction zone is matched with the scale provided on the container. Five colour zones corresponding to 9, 10, 20, 50, 100 mg/l of albuminuria are shown on the scale.

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The absorbed urine enters a zone on the strip containing soluble antibody-enzyme conjugate which specifically binds to albumin. Excess conjugate is retained in a separate zone containing immobilised human albumin so that only the conjugated immuno complex from the sample reaches the reaction zone. Here the enzyme B-galactosidase reacts with the substrate, producing a red dye, the intensity of which after exactly 5 minutes is directly related to the albumin content of the urine.

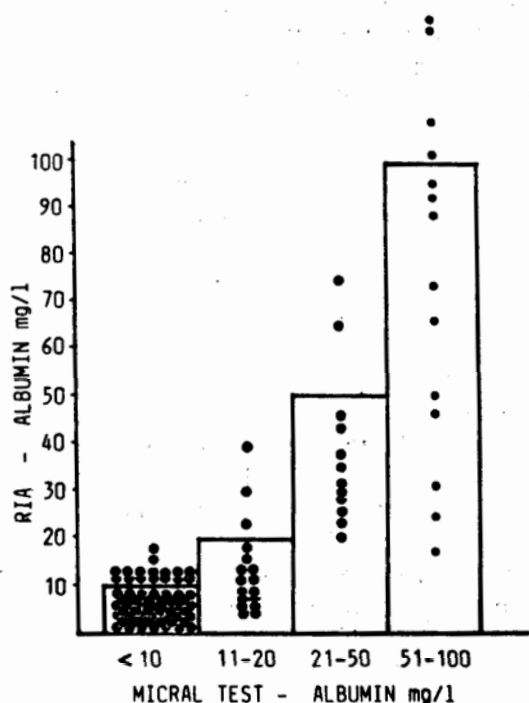


Figure shows the comparison of individual values of MA estimated by the RIA procedure and the Micral test. The vertical columns show the semiquantitative range of MA estimated by the Micral test. The values determined by the RIA are shown by the scatterogram marked on the respective semiquantitative range.

RESULTS

Microalbuminuria (albumin excretion of ≥ 20 mg/l) was present in 28 patients (23.3%). Figure 1 shows the relation between the semiquantitative estimate and the albuminuria estimated by the RIA. The 4 blocks represent the semiquantitative range. The overall sensitivity of the Micral test was 89% ie it detected 25/28 positive cases in the study. The specificity of the test was 99% as one normal value was shown in the abnormal range. In comparison with the RIA values, 95%, 83% and 78% of the values in < 20 mg/l, > 20 to 50 mg/l and > 50 to 100 mg/l zones were within the range.

CONCLUSIONS

The Micral test is found to be a rapid and reliable procedure for semiquantitative estimation of microalbuminuria. It provides a simple procedure for screening for MA and is a sensitive and specific test. In addition to providing a quick assessment of the albuminuria, it also helps to select the positive samples where exact quantitation is necessary.

REFERENCES

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