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Introduction: Microalbuminuria allows the identification of patients under cardiovascular risk, as well as the diagnosis and early treatment of diabetic nephropathy. In Latin-American countries, approximately 32% (18 %-66 %) of type 1 and 25% (17%-49%) of type 2 diabetic patients has access to having microalbuminuria tested; this is why the determination of the clinical validity of standardized, quick and low-cost methods for screening campaigns should be considered a priority. **Aim:** To determine the clinical validity of simple, low-cost techniques for the determination of microalbuminuria, comparing them to a reference method. **Methods:** The albuminuria/creatininuria ratio was determined for 151 12-h urine samples from diabetic patients. Each sample was assayed for albuminuria by three methods: radioimmunoassay (DPC double antibody, considered as reference method) DCA 2000® (Bayer) and Clinitek® (Bayer), according to the instructions provided by the manufacturer. The following parameters were obtained: sensitivity (S), specificity (E) and predictive value (PV). The Spearman correlation coefficient, the ROC curves analysis and the Kappa statistic were used for comparison. **Results:** According to the albuminuria/creatininuria ratio, 15% of the samples had confirmed presence of microalbuminuria. The RIA and DCA 2000 methods proved to be significantly correlated (r=0.70, CI 95%=0.60-0.76). When the ability of both methods for detection of the presence of microalbuminuria was evaluated by the ROC analysis, no significant difference was observed, with an area under the ROC curve close to 100% (0.945 and 0.955 for DCA and RIA, respectively). All three methods showed results in accordance with the clinical state of the patients (Kappa coefficients above 0.8). Considering a cutoff value of 30 mg/g, S and E results were 95.7% and 89.9% for DCA and 82.6% and 96.4% for Clinitek. **Conclusions:** No differences were found between DCA and RIA methods in terms of their discriminative power. The S and E values obtained for DCA and Clinitek methods were conveniently high. This makes Clinitek a suitable technique when a fast, reliable, high-efficient, low-cost method is sought for a diabetic nephropathy screening campaign, considering the drawbacks presently faced by the early diagnosis of this disease in most Latin-American countries.

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Aim

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Methods and Procedure

The albuminuria/creatininuria ratio was determined for 151 12-h urine samples from diabetic patients. Each sample was assayed for albuminuria by three methods: radioimmunoassay (DPC double antibody, considered as reference method) DCA 2000® (Bayer) and Clinitek® (Bayer), according to the instructions provided by the manufacturer. The following parameters were obtained: Sensitivity, Specificity and Predictive Value. The Spearman correlation coefficient, the ROC curves analysis and the Kappa statistic were used for comparison.

Results

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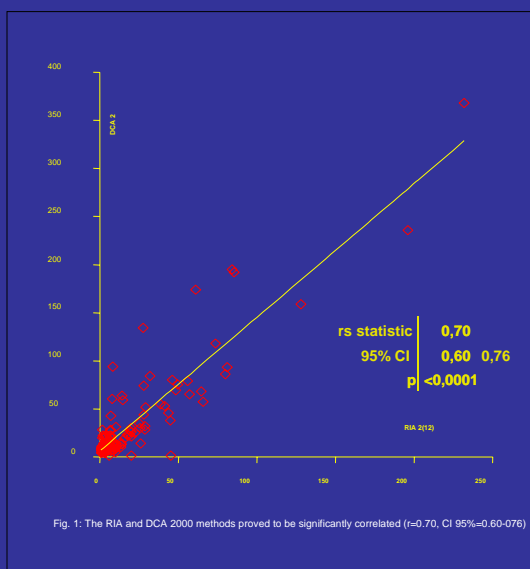


Fig. 1: The RIA and DCA 2000 methods proved to be significantly correlated (r=0.70, CI 95%=0.60-0.76)

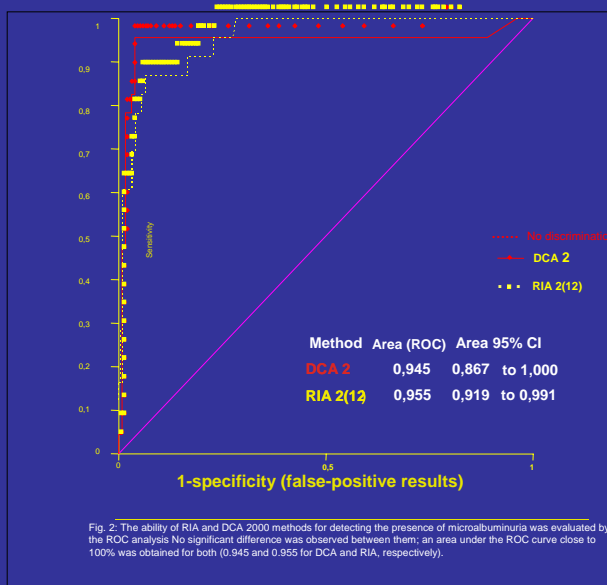


Fig. 2: The ability of RIA and DCA 2000 methods for detecting the presence of microalbuminuria was evaluated by the ROC analysis. No significant difference was observed between them; an area under the ROC curve close to 100% was obtained for both (0.945 and 0.955 for DCA and RIA, respectively).

Validation parameters

	DCA	95% CI	Clinitek	95% CI
Sensitivity	95,7%	78,1% - 99,9%	82,6 %	78,9 – 97,5%
Specificity	89,9%	83,4% - 94,5%	96,4 %	94,5 – 99,8%
Global Efficiency	91%		96%	

These values were obtained considering a cut off value of 30 mg/g creatinine

Method – Disease concordance

	DCA	Clinitek
Kappa Statistic	0,84	0,84
(concordance estimator)		

All three methods showed results in accordance with the clinical state of the patients (Kappa coefficients above 0.8).

Conclusions

No differences were found between DCA and RIA methods in terms of their discriminative power. Sensitivity and Specificity values obtained for DCA and Clinitek methods were conveniently high. This makes Clinitek a suitable technique when a fast, reliable, high-efficient, low-cost method is sought for early diagnosis of diabetic nephropathy