THE USE OF HEMOCUE® ALBUMIN 201 AS AN EPIDEMIOLOGICAL SCREENING METHOD FOR MICROALBUMINURIA

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INTRODUCTION : Microalbuminuria (MA) is an emerging risk factor for cardiovascular and kidney disease leading to a growing interest in establishing screening programmes. HemoCue® Albumin 201 analyser (HC) is an immunoturbidimetric method for quantifying urine albumin concentration (UAC) at the point of care (POC), with detection range 5 -150 mg/L. Its use in analysing non-fresh urine samples from epidemiological screening programmes has not been validated. In this study, we investigated the validity of HC compared to a standard nephelometric method.

METHOD : Early morning urine samples obtained by post as part of a screening programme for MA in a cohort of overweight and obese residents in the city of Sheffield (The Kidney Evaluation of Obese Population of Sheffield [KEOPS] Study) were tested using HC as well as a standard laboratory method of nephelometry (Dade-Behring (D-B) BNII instrument). Creatinine was measured using a Jaffe method to determine albumin creatinine ratio (ACR). Linear regression was used to assess the correlation between HC and the reference laboratory method. An ROC curve was constructed to evaluate the sensitivity and specificity of HC in detecting ACR > 2.0 mg/mmol at different cut-off points of UAC.

RESULTS : Forty one (41) samples were analysed. Of those, 33 samples had UAC within the detection range of HC analyser and were used for statistical analysis. Linear regression between HC and the reference method reveals a Pearson correlation coefficient of r=0.945, r^2=0.893. A Bland-Altman plot looking for systematic bias is shown in figure 2. The area under the ROC curve (95% CI) is 0.924 (0.82-1.0). For HC measured UAC of >19 mg/L the sensitivity and specificity for detecting MA are 67% and 86% respectively. Using a cut-off value of 15.5 mg/L the sensitivity improves to 83 % with a specificity of 83%.

DISCUSSION : The correlation coefficient between HC and the standard laboratory method in non-fresh urine samples of r^2=0.89 is less than that reported at the POC. We defined an ACR of greater than 2.0 mg/mmol as positive which is lower than the conventional 2.5-3.5 mg/mmol. This is to account for possible degradation of albumin with prolonged uncontrolled storage during postage. For this level of ACR, a cut-off value of HC measured UAC of 15 mg/L provides better sensitivity and specificity than the manufacturer's recommended value of 20 mg/L. We realise that the study is small, but overall we feel that HC may be a reliable method for MA screening in non-fresh urine samples.

Figure1 – Correlation between HC and nephelometry

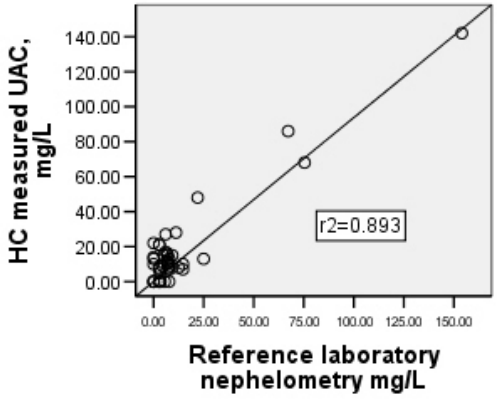

Figure 2- Bland –Altman plot