Is the Bayer DCA 2000 acceptable as a screening instrument for the early detection of renal disease?

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Additional key phrases: early renal disease; urine albumin:creatinine ratio; specificity; predictive value for microalbuminuria

The analytical capabilities of the Bayer DCA 2000 System point-of-care instrument (Bayer Australia Ltd, Pymble, NSW, Australia) have recently been upgraded to include the measurement of the urine albumin:creatinine ratio (ACR).¹ Microalbuminuria, defined as a urine ACR between 3:4 and 34 mg/mmol for females and between 2:5 and 34 for males,² is a well-established predictor for diabetic nephropathy and clinical proteinuria in the non-diabetic.³ The use of the urine ACR measurement as a screening test for the early detection of renal disease in high-risk population groups, such as Aboriginal Australians, has recently been advocated.⁴,⁵

Through a co-operative partnership with the Umoona Tjutagku Health Service, the Renal Unit at Flinders Medical Centre has recently begun a program for the early detection and prevention of renal disease with the 500-strong Umoona Aboriginal community at Coober Pedy in South Australia’s far north. The first phase of the study involves screening the community for its risk factors for renal disease, the cornerstone of which is the measurement of urine ACR. The Bayer DCA 2000 instrument was selected as the instrument of choice for this phase of the program, but prior to its implementation, the analytical and diagnostic performance characteristics of the machine were evaluated.

METHODS AND PATIENTS

The Bayer DCA 2000 instrument uses a reagent cartridge (Bayer DCA 2000 Microalbumin/ Creatinine Catalogue Number 0611) which provides a quantitative measurement of albumin (by immunoturbidimetry, using a polyclonal goat anti-human albumin antiserum) and creatinine [by spectrophotometry using 3,5-dinitrobenzoic acid (DNBA) at alkaline pH], as well as calculation of the ACR, all within a 7-min window. Common potential interfering substances with colorimetric urine creatinine methods, such as glucose, acetoclastic acid, bilirubin and cephalolothin, were shown by Bayer to produce a bias of less than ±5% using the DNBA method.⁶ The measuring ranges of the instrument are: urine albumin 5 to 300 mg/L, urine creatinine 1:3 to 44:2 mmol/L, and urine ACR 0:11 to 226 mg/mmol. Calibration parameters are encoded onto a calibration card provided with each reagent kit (which contains ten cartridges). Urine albumin, creatinine and ACR results are displayed for each test sample.

Low and high control samples (Bayer DCA 2000 Microalbumin/Creatinine Low and High Control kit, Catalogue Number 6012) were analysed daily on the DCA 2000 over a 15-day period to assess between-run imprecision.

Sixty random, spot urines from diabetic subjects (64% males and 36% females) were analysed over a 30-day period by both the DCA 2000 (using six reagent kits) and by routine methods at the SouthPath laboratory, Flinders Medical Centre [urine albumin by nephelometry using the Beckman Array (Beckman Instruments Inc, Fullerton CA, USA) and urine creatinine by a kinetic Jaffe method on an Hitachi 917 (Boehringer Mannheim GmbH, Mannheim, Germany)]. These urines had a range of concentrations/ ratios (by the SouthPath methods) of urine albumin 4 to 235 mg/L, urine creatinine 2 to 24 mmol/L, and urine ACR 0:4 to 34 mg/mmol.

RESULTS

Between-day coefficients of variation (n = 15) for each measurement on the DCA 2000 were: 3.0% and 2.4% for urine albumin (at levels of 34 and 201 mg/L, respectively), 2.1% and 1.8% for
urine creatinine (8·8 and 36·7 mmol/L), and 3·4% and 2·3% for urine ACR (for ratios of 3·8 and 5·5). These levels of imprecision are better than those achieved by the top 20% of laboratories participating in the Royal College of Pathologists of Australasia—Australasian Association of Clinical Biochemists Chemical Pathology Quality Assurance Programs group (8·2% for urine albumin, 2·4% for urine creatinine, June 1998 cycle) (J Gill, personal communication).

For the 60 urines tested, the DCA 2000 showed excellent correlation with the SouthPath methods (regression analysis slopes = 1·05, 1·03 and 0·99, and r = 0·99, 0·99 and 1·00 for urine albumin, urine creatinine and urine ACR, respectively).

The figure displays the difference in results between the two methods for urine ACR. The overall mean difference for ACR between the two methods was 0·119 (standard error 0·071); P = 0·100, not significant.

Of the 60 urines tested, 34 (57%) were classified as normal and 26 (43%) as microalbuminuric (ACR between 3·4 and 34 mg/mmol) by the SouthPath methods. There was only one urine sample where a difference in diagnostic classification for microalbuminuria would have been made using the DCA 2000 (SouthPath ACR 2·8, normal; DCA 2000 ACR 3·8, microalbuminuria—false positive). The DCA 2000 thus exhibited the following comparative diagnostic performance characteristics for microalbuminuria: sensitivity 100%, specificity 97%, predictive value of a positive test 96%, and predictive value of a negative test 100%.

CONCLUSION

This evaluation showed that the Bayer DCA 2000 provides a precise, accurate and diagnostically reliable measurement of urine ACR. In addition to its analytical capabilities, the DCA 2000 has many other characteristics which make it an ideal screening instrument for the early detection of renal disease in a remote clinical setting, such as the Umoona Aboriginal community at Coober Pedy; it is portable, simple to use, requires no sample or reagent preparation, provides quick turnaround of results (7 min) and is cost effective (an ACR on the DCA 2000 being over three times less expensive than the standard government reimbursement for a laboratory urine albumin and urine creatinine determination).

REFERENCES