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RESEARCH ARTICLE

PRECISION ANALYSIS OF URINARY MICRO-ALBUMIN ON CONVENTIONAL HITACHI 912 AND MODULAR COBAS 6000 C501 ANALYZERS

***,[1]Junaid Mahmood Alam, [1]Humaira (Howrah) Ali, [2]Jawed Altaf Baig, [1]Aijaz Ahmed and Sheikh Matinuddin**

[1]Department of Biochemistry Lab Services and Chemical Pathology, Liaquat National Hospital and Medical College, Karachi, Pakistan
[2]Department of Biochemistry, Liaquat National Medical College, Karachi, Pakistan

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ABSTRACT

Background: Clinical significance of urinary micro-albumin in diabetes, cardiovascular disease and hypertension generated interest amongst scientist, researchers and clinicians to enhance its measurement accuracy and level of precision.
Aim and Objectives: Present study describes the comparative precision analysis of urinary micro-albumin on conventional Hitachi 912 chemistry analyzer and modular Cobas 6000 c501 system.
Material and Methods: A total 240 patients (Males = 120, Females = 120), n = 40 for each disease (Diabetes, Hypertension, Renal disease) in both genders, were selected for the present study during Dec 2013 to Dec 2014. Determination of micro-albumin was performed in 2nd morning urine collected from all patients and co-morbid groups and analyzed in duplicate using TINA-QUANT albumin methodology (Roche Diagnostics).
Results: Comparative precision analyses data showed 93% to 97% correlation of analytical precisions among both conventional Hitachi and Cobas modular systems, thus guaranteeing equitable quality assurance of methods and instrumentations.
Conclusion: It was concluded that 93% to 97% linear linked precision existed in analytical steps of conventional and modular system with R^2 0.93 to 0.97 in various clinical groups of patients, suggesting considerable unbiased accurateness.

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INTRODUCTION

Elevated urinary excretion of protein components, especially micro-albumin, is stated to be an early indicator of glomerular insufficiency, leading most of the time to renal failure (Sviridov *et al.,* 2008; Sinwat *et al.,* 2012). Moreover, even if the urinary micro-albumin excretion is within the normal range of less than 30 mg/24 hours, it is still considered as a risk factor for mortality and development of cardiovascular anomalies (Viberti *et al.,* 1982; Arnlov *et al.,* 2005; Wang *et al.,* 2006). Such noted clinical significance of estimation of urinary micro-albumin generated further interest amongst scientist, researchers and clinicians in several countries to enhance its measurement accuracy and level of precision (Afkhami-Ardekani *et al.,* 2008; Silva *et al.,* 2008; Sviridov *et al.,* 2008).

Corresponding author: Junaid Mahmood Alam
Department of Biochemistry laboratory services, Liaquat National Hospital and Medical College, Karachi, Pakistan.

In recent years, development have been made in upgrading analytical principles and techniques, in addition to precision and sensitivity of several conventional methods and equipments regarding protein and hormonal components (Alam *et al.,* 2014a,b). Furthermore, it is also now considered as an imperative norm to upgrade conventional analytical systems to modular and efficient ones, which can generate more precise and better quality results to cater tertiary care hospitals and middle to large size clinical laboratories. In this regard, the present study describes the comparative precision analysis of urinary micro-albumin on two systems, the conventional Hitachi 912 chemistry analyzer and modular Cobas 6000 c501 system.

MATERIALS AND METHODS

Materials: A total 240 subjects (Males = 120, Females = 120) were selected for the present study conducted at Department of

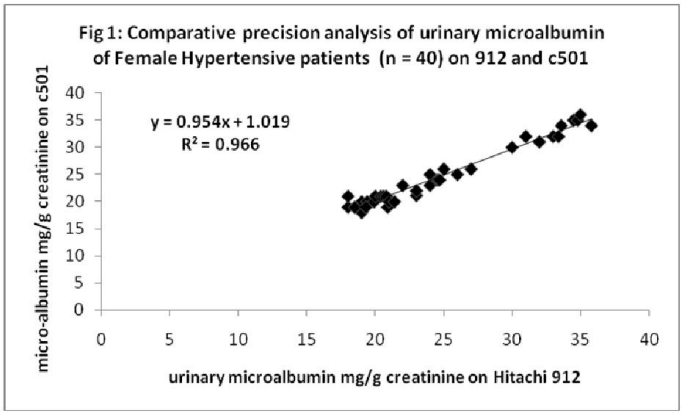
Biochemistry Lab services & Chemical Pathology, Liaquat National Hospital and Medical College during Dec 2013 to Dec 2014. The patients' selection were based on the confirmation of micro-albuminuria in diabetes mellitus with renal disease (n = 80) and hypertension (n = 80), sub classified as males and females with n = 40 patients each. Renal insufficiency was considered significant when protein to creatinine ratio was greater than 1.0; and patients were categorized as diabetic where fasting was greater than 125 mg/dl or HbA1c greater than 8.0%. The patients were considered hypertensive that manifested blood pressure equal or higher than 140/90 mmHg. The average ages of patients in groups and sub-groups were renal insufficiency: F = 32-75 yrs, M = 29-80 yrs; diabetics F = 28-76 yrs, M = 31-82 yrs and hypertensive: F = 33-69 yrs and M = 34-78 yrs.

Analysis of urinary micro-albumin: Determination of micro-albumin was performed in 2nd morning urine collected from all patients and co-morbid groups. The samples were analyzed in duplicate using TINA-QUANT albumin methodology on conventional Hitachi 912 chemistry analyzer and modular Cobas 6000 c501 (Roche-Diagnostics, Pakistan and Basil) as per manufacturer's advices.

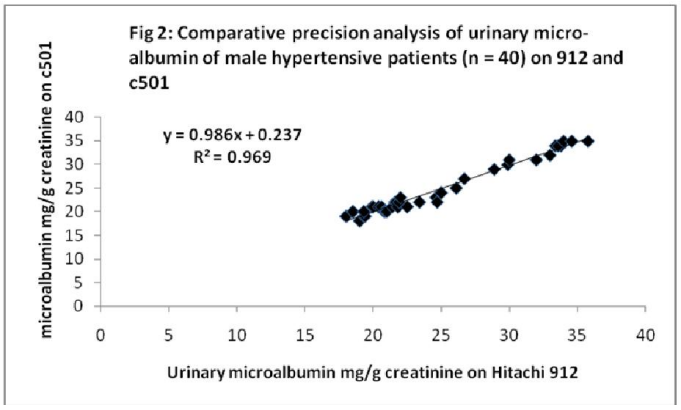
Statistical analysis: Data are presented as mean ± standard deviation and statistically compared with $P < 0.05$. Regression correlation analysis was performed by comparing data generated by Hitachi 912 on X axis and Cobas 6000 c501 on Y axis.

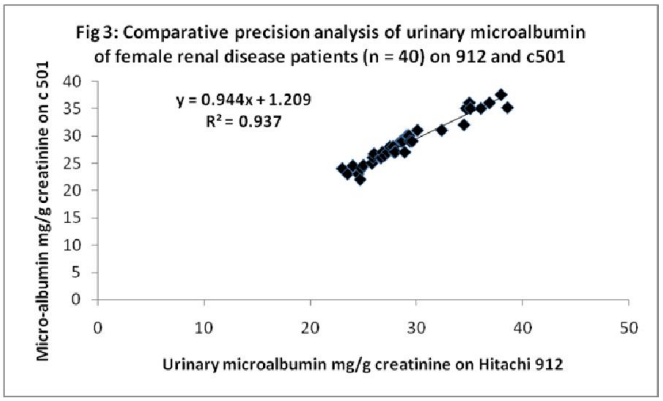
RESULTS

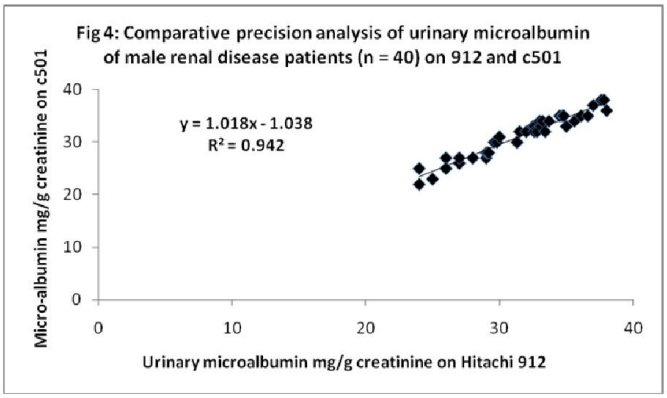
The results are summarized in Figs. 1 to 6. Comparative precision analysis of urinary micro-albumin depicted appreciable regression correlation of results that were analyzed on conventional Hitachi 912 chemistry analyzer and the modular Cobas 6000 c501 system. The mean value of micro-albumin in renal disease group was 31.28 ± 6.80 mg/g creatinine in males and 28.77 ± 7.10 mg/g creatinine in females; in Hypertensive 24.32 ± 9.16 mg/g creatinine and 24.67 ± 8.12 mg/g creatinine in males and females, respectively.

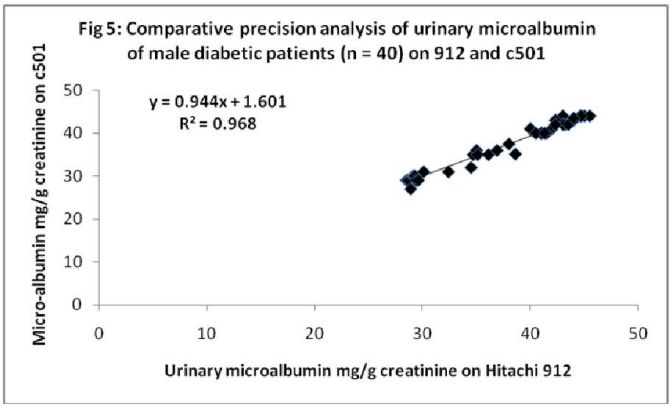


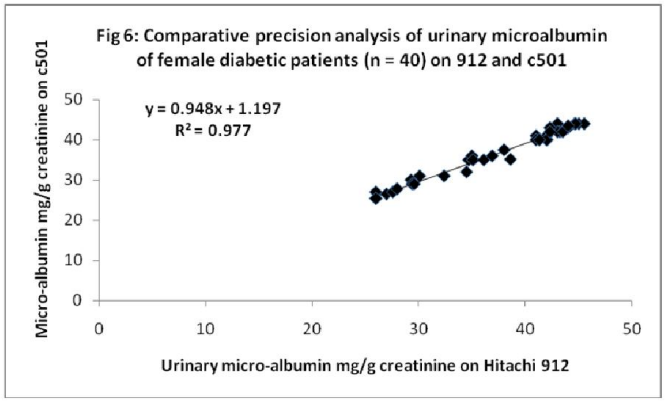
Regression correlation analysis exhibited significant correlation between precision of micro-albumin analysis on conventional Hitachi analyzer and modular Cobas 6000 c501, depicted by R^2 value of approximately 0.96 in both male and female hypertensive group (Fig. 1, 2), 0.94 and 0.93 in males and females Renal disease group (Fig. 3, 4) and 0.96 and 0.97 in male and female diabetic patients group (Fig. 5, 6), respectively.











Comparative precision analyses data thus manifested around 93% to 97% correlation of analytical precisions among both conventional and modular systems, thus guaranteeing equitable quality assurance and control of methods and instrumentations.

DISCUSSION

Determination of urinary micro-albumin by immuno-turbidimetric method is in use since 1987 on both semi-automatic and conventional Hitachi chemistry auto-analyzer series 704, 705, 911 and 912 (Landgraf-Leurs *et al.,* 1987). This method has the advantage of being economical and has the ability to detect micro-albumin at minimal concentrations (Viberti *et al.,* 1982; Mogensen *et al.,* 1984; Landgraf-Leurs *et al.,* 1987; Sinwat *et al*., 2012). Previous studies on estimating the laboratory precision of urinary micro-albumin exhibited appreciable correlation among the techniques used and instruments (Dinneen and Gerstein, 1997; Dyer *et al.,* 2004; Liu *et al.,* 2011; Dupuy *et al*., 2014). Methodological evaluation for urinary micro-albumin was also carried out earlier with comparison of five referred analytical principles of nephelometry, turbidimetry, colloidal gold method, radio-immunoassay and electro-chemi-luminescence (Liu *et al.,* 2011). Moreover, in another earlier study, immuno-turbidimetric assay for analysis of urinary micro-albumin was stated to be superior to High performance liquid chromatography (Contois *et al.,* 2006). In our study 3rd generation (Gen3) immuno-turbidimetric method was used to determine urinary micro-albumin on both stand-alone conventional Hitachi 912 chemistry analyzer and the modular Cobas 6000 c501. It was noted that 93% to 97% linear correlated precision existed in analytical steps of both instruments with R^2 0.93 to 0.97 in various clinical groups of patients, suggesting significant equitable correctness. More recently a study reported comparison of immuno-turbidimetric method on Cobas c502/Cobas 8000 for urinary microalbumin (Dupuy *et al.,* 2014). The study concluded that immuno-turbidimetric method for albumin determination was accurate and contains required precision in that dedicated instrument. Few previous studies also dealt with several methodologies, accuracy issues and standardization of reference methods for urinary micro-albumin, of which national kidney disease foundation program and IFCC working group on standardization study was of significant importance (Speeckaert *et al.,* 2011). The group concluded that usage of polyclonal antisera for immuno-chemistry/ immunoturbidimetric determination of albumin shall remain the gold standard.

Conclusion

The present study describes the comparative precision analysis of urinary micro-albumin on conventional Hitachi 912 chemistry analyzer and modular Cobas 6000 c501 system. . It was noted that 93% to 97% linear linked precision existed in analytical steps of both instruments with R^2 0.93 to 0.97 in various clinical groups of patients, suggesting considerable equitable accuracy.

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