COMPARISON OF FREELITE™ AND N LATEX SERUM FREE LIGHT CHAIN ASSAYS IN SUBJECTS WITH END STAGE RENAL DISEASE ON HAEMODIALYSIS

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BACKGROUND
Quantification of serum free light chains (FLC) is important in the diagnosis of plasma cell dyscrasias, where abnormal kappa:lambda ratio infers a population of monoclonal plasma cells. The Freelite™ assay and N Latex assay have been validated in a non-chronic kidney disease population but there is a paucity of data relating to these assays in the end stage kidney disease population. The aim of this study was to compare the N Latex and Freelite™ assays in a larger haemodialysis (HD) population without plasma cell or lymphoproliferative disorders and to define reference ranges in this population.

METHODOLOGY
- Study subjects: 112 haemodialysis patients without known paraproteinaemia (7 were subsequently excluded).
- Study design: a cross-sectional study comparing serum FLC pre- and post-haemodialysis using N Latex (Siemens Healthcare, Germany) and Freelite™ (The Binding Site Ltd, UK) serum FLC assays.
- Other laboratory analyses: monthly routine chemistry and haematology testing, screening for immunofixation (Gebra, France) pre-HD samples.
- Statistics: results expressed as mean (SD) for normally distributed values or median (interquartile range) for non-normally distributed values. Bias was determined by Bland-Altman.

RESULTS

Comparison of N Latex and Freelite assays

Kappa FLC levels were elevated by both assays. Pre-HD median kappa FLC was 160 mg/L by Freelite and 130 mg/L by N Latex. Post-HD kappa FLC decreased but remained above normal with minimal discrepancy between assays.

Lambda FLC levels were elevated by both assays. Pre-HD median lambda FLC was 210 mg/L by Freelite and 110 mg/L by N Latex. N Latex was on average 141 mg/L (95% CI 20 to 261 mg/L) higher than Freelite (see Bland-Altman plot).

Dialysis produced a two-thirds reduction in both kappa and lambda FLC by N Latex and in kappa FLC by Freelite. Clearance of lambda FLC was less with Freelite compared to N Latex, with only a one-third reduction in the pre-dialysis value. Lower kappa:lambda FLC ratio by N Latex was due to lambda FLC reading significantly higher by the N Latex assay.

The difference in clearance of the lambda FLC on dialysis of 64% by N Latex and 41% by Freelite remains unexplained.

CONCLUSIONS
Our clinical study of 105 consecutive patients demonstrated high concordance between N Latex and Freelite assays but identified significant numerical discrepancy between the two assays. We demonstrated that patients with ESKD on dialysis have FLC concentrations well above the normal range and that dialysis fails to normalise these.

We confirmed the need for a renal reference range for kappa:lambda FLC ratio when using the Freelite assay but not for the N Latex assay. The results of this study are most relevant to clinical haematologists and nephrologists interested in excluding, diagnosing and managing plasma cell dyscrasias in patients on haemodialysis.

Further investigation is required to explain the observed discrepancies between the two assays. Lambda light chain concentrations are higher by N Latex than by Freelite especially for pre-haemodialysis samples. Further investigation is required to explain the observed discrepancies between the two assays.

Clinicians and laboratories should be aware of the need for a separate renal reference range for interpreting FLC ratio using the Freelite assay but not for the N Latex assay.