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Structure submission process:
a. Presenting Author Information
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f. Abstract Title
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h. Disclosure
i. Review and Submit Abstract

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Abstract details

Theme
Chronic kidney disease

Topic
Chronic kidney disease diagnosis, classification and progression

Consider for a Young Nephrologists Award
Do not consider for a Young Nephrologists Award

Presentation preference
Oral OR Poster Presentation

Abstact number
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Abstract title
A PILOT STUDY: MANIFESTATION OF CANDIDATE RENAL BIOMARKERS IN PATIENTS WITH CHRONIC KIDNEY DISEASE OF UNCERTAIN ETIOLOGY

Keywords
Novel, renal, biomarkers, CKDu, Sri Lanka

Introduction
Renal biomarkers in current practice, urine albumin and serum creatinine, are inaccurate for early detection of Chronic Kidney Disease of uncertain etiology (CKDu) and discrimination of CKDu from other chronic renal diseases. Aim of the pilot study is to evaluate “fit for purpose” biomarkers or biomarkers that manifest in CKDu. Novel candidate renal biomarkers in clinical validation phase can be used for this purpose. Luminex xMAP, a robust analytical platform can assay multiple analytes in a small sample volume (< 50 µL) at picogram level that comply with this study.

Methods
80 biopsy proven stage 1-3 CKDu patients (Nanayakkara, 2011) were selected from renal clinics using a systematic sampling method. Urine and serum samples were collected and stored in -80°C refrigerator according to biological sample collection for clinical proteomics SOPs. Total of 27 renal candidate biomarkers were included in customized magnetic bead based multiplexed assay kits (four serum and two urine Millipore kits). Samples were prepared with duplicates of blank (1), standards (6), quality controls (2), and patients (39) on a 96 well microtiter plate, according to the manufacturer's instructions. Samples were analyzed on Luminex MAGPIX analyzer. The biomarker concentrations in the samples were determined from the 5-parameter logistic fit standard curves created in Milliplex analyst software. The manifestation of a biomarker in CKDu was deduced from number of samples within detectable range. The percentages for each biomarker was tested at 5% of significant level ($H_{o:}$ $P \leq 0.8$ Vs H_a: $P > 0.8$) to extract the biomarkers which exceeds significantly > 80% of cases within detectable range (One sample proportion test).

Results
Results of candidate renal biomarkers in 80 CKDu patients

Analyte	Detectable Concentration Range		% detected within range*
	min-DC	max-DC	
Serum			
TGF-β	5.01 ρ	3789 ρ	100
RBP-4	0.13 ρ	18978 ρ	0.00 (all > max-DC)
β2MG	0.035 ρ	29453 ρ	100
Cystatin C	0.062 ρ	5283 ρ	100
NGAL	0.05 ρ	4442 ρ	57 (43 > max-DC)
TIMP-1	5.14 ρ	655.91 ρ	99
Collagen-IV	0.52 ρ	988.42 ρ	100
IL-10	13.10 ρ	738.13 ρ	21 (79 < min-DC)
IL-6	2.45 ρ	221.41 ρ	29 (69 < min-DC)
TNF R11	3.58 ρ	6555 ρ	96
OPG	5.27 ρ	793.05 ρ	96
KIM-1	24.89 ρ	865.44 ρ	24 (76 < min-DC)
Pentaxin-3	9.66 ρ	4904 ρ	96
Renin	86.04 ρ	25632 ρ	88
PTH	1.99 ρ	251.98 ρ	96
FGF-23	23.68 ρ	1044 ρ	34 (66 < min-DC)
Urine			
NGAL	0.0088 η	559.32 η	100
RBP-4	0.043 η	7511 η	24 (76 > max-DC)
β2MG	0.56 η	19252 η	48 (52 > max-DC)
Cystatin C	0.02 η	1981 η	99
OPN	28.74 η	2198 η	99
α1MG	125.55 η	42130 η	83
TIMP-1	0.25 η	58.76 η	93
KIM-1	0.05 η	1.34 η	92
FABP-1	8.49 η	53.34 η	49 (51 < min-DC)
Collagen-IV	018 η	340.92 η	100
TFF-3	0.25 η	1170 η	99

* number of cases within detectable concentration (DC) as a percentage of the total number of cases, ρ = pg/ml, η = ng/ml.

Conclusions

Serum (n = 10) TGFβ-1, β2MG, Cystatin C, TIMP-1, Collagen-IV, TNF RII, OPG, Pentaxin-3, Renin, PTH and urine (n=8) NGAL, Cystatin C, OPN, α1MG, TIMP-1, KIM-1, Collagen-IV, TFF-3 are fit for validation of CKDu. Serum IL-10, IL-6, KIM-1, FGF-23 and urine FABP-1 are not manifested in majority whereas serum NGAL, urine β2MG and RBP-4 in both matrices are detected above the max-DC in all cases, and we may further dilute the samples to get within the range.

Declaration

No conflict of interest