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Unwrapping the GIFT Panel: Technical Feasibility and Preliminary Signals of a Novel Multi-Biomarker Panel for DKD Progression in Type 2 Diabetes Mellitus

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Objectives : Albuminuria and eGFR detect DKD progression only after irreversible structural injury, leaving a critical early intervention window unaddressed. DKD is mechanistically heterogeneous simultaneously engaging glomerular injury, tubular damage, and inflammatory-fibrotic cascades yet no validated multi-pathway urinary biomarker tool exists for early-stage risk stratification. We introduce the GIFT (Glomerular-Inflammatory-Fibrotic-Tubular marker) panel comprising CTGF, Cystatin C, KIM-1, NGAL, TNF-α, MCP-1, and TGF-β, and evaluate its analytical feasibility and prognostic signals across CKD stages 1–3b in Type 2 Diabetes Mellitus.
Methods : This prospective observational pilot study (November 2024–March 2025) enrolled 40 adults with T2DM-associated CKD at KMC Manipal, India. Baseline biospecimens were quantified by seven-plex ELISA validated by four-parameter logistic (4PL) regression with inverse prediction. Rapid progression was defined as an eGFR decline of ≥5 mL/min/1.73 m²/year (CKD-EPI) over 12 months of follow-up. Discrimination was assessed by ROC-AUC analysis; leave-one-out cross-validation (LOOCV) estimated optimism-adjusted panel performance. Subgroup analyses were stratified by albuminuria category.
Results : Thirty-nine patients were evaluable; 12 (30.8%) were rapid progressors. All 7 4PL assays converged with validated inverse-prediction accuracy. Individually, CTGF demonstrated the strongest discrimination (AUC 0.670; 95% CI: 0.473–0.866; sensitivity 75%) and approached independent significance on multivariate analysis (p=0.064). The apparent combined panel AUC of 0.716 collapsed to 0.370 under LOOCV (optimism=0.346), confirming overfitting at this event-to-predictor ratio and the necessity of the planned whole cohort (n=145). Albuminuria-stratified analyses revealed distinct stage-specific signals: CTGF achieved an AUC of 0.750 in the microalbuminuria subgroup, while Cystatin C reached an AUC of 0.756 in macroalbuminuric patients.
Conclusions : The GIFT panel establishes robust analytical feasibility and generates biologically coherent, albuminuria-contextualised prognostic signals consistent with DKD's mechanistic heterogeneity. Definitive panel-level inference awaits the fully powered validation cohort.

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Characteristic	Overall N = 39[1]	Non-Progressor N = 27[1]	Progressor N = 12[1]	p-value[2]
Age	62 (55, 69)	62 (58, 70)	58 (54, 68)	0.3
Males	34 (87%)	25 (93%)	9 (75%)	0.2
BMI	26.0 (23.5, 29.5)	25.9 (23.0, 27.2)	28.7 (25.8, 29.8)	0.091
Duration of Diabetes (years)	12 (10, 20)	15 (10, 21)	12 (12, 18)	>0.9
Stage of CKD				0.5
1	3 (7.7%)	1 (3.7%)	2 (17%)	
2	5 (13%)	3 (11%)	2 (17%)	
3a	13 (33%)	10 (37%)	3 (25%)	
3b	18 (46%)	13 (48%)	5 (42%)	
Systolic BP (mmHg)	140 (130, 153)	140 (130, 150)	142 (140, 162)	0.3
Diastolic BP (mmHg)	80 (70, 90)	76 (64, 90)	83 (73, 94)	0.054
Hypertension Duration (yrs)				0.13
0–5	14 (35.9%)	11 (40.7%)	3 (25.0%)	
6–10	7 (17.9%)	3 (11.1%)	4 (33.3%)	
11–15	10 (25.6%)	6 (22.2%)	4 (33.3%)	
16–20	5 (12.8%)	4 (14.8%)	1 (8.3%)	
21–25	1 (2.6%)	1 (3.7%)	0 (0.0%)	
26-30	2 (5.1%)	2 (7.4%)	0 (0.0%)	
H/o Diabetic Retinopathy	19 (49%)	13 (48%)	6 (50%)	>0.9
HbA1c (%)	7.20 (6.40, 9.00)	7.20 (6.20, 9.00)	7.25 (6.50, 8.60)	0.5
eGFR (ml/min/1.73m²)	45 (34, 57)	43 (34, 53)	47 (34, 68)	0.5
Serum Creatinine	1.70 (1.35, 2.04)	1.78 (1.38, 2.06)	1.55 (1.20, 1.92)	0.3
Albuminuria Category				0.051
Normo (A1)	4 (10%)	3 (11%)	1 (8.3%)	
Micro (A2)	16 (41%)	14 (52%)	2 (17%)	
Macro (A3)	19 (49%)	10 (37%)	9 (75%)	
Serum Urea	42 (30, 60)	43 (30, 62)	39 (30, 49)	0.6
Serum Sodium	138.00 (137.00, 140.00)	139.00 (138.00, 141.00)	137.00 (135.50, 138.00)	0.04
Serum Potassium	4.70 (4.40, 5.10)	4.70 (4.30, 5.10)	4.90 (4.60, 5.30)	0.3
Cystatin C (ng/mL)	301 (255, 561)	288 (242, 485)	327 (261, 938)	0.3
KIM-1 (pg/mL)	111 (74, 224)	105 (73, 196)	116 (93, 270)	0.4
NGAL (ng/mL)	5 (4, 8)	5 (3, 8)	5 (4, 7)	0.8
TNF-α (pg/mL)	71 (38, 109)	57 (38, 107)	75 (41, 139)	0.4
MCP-1 (pg/mL)	644 (267, 1,503)	644 (199, 1,503)	659 (387, 1,472)	0.5
TGF-β (pg/mL)	19 (6, 43)	17 (1, 52)	30 (9, 38)	0.7
CTGF (pg/mL)	4,184 (2,973, 5,536)	3,705 (2,930, 5,200)	4,620 (3,643, 7,267)	0.1

[1]Median (Q1, Q3); n (%); [2]Wilcoxon rank sum test; Fisher's exact test; Wilcoxon rank sums exact test; Pearson's Chi-squared test

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