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Prospective Study to Evaluate the Effectiveness of Donor-derived Cell-free DNA for Early Diagnosis of Acute Rejection in Renal Transplant Recipients

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Objectives: In this study, we investigated to verify whether the titer of donor-derived cell-free DNA (dd-cfDNA) has diagnostic value in predicting acute rejection in kidney transplant recipients (KTR).

Methods: This study was prospectively designed to verify the effectiveness of dd-cfDNA for the diagnosis of acute rejection in KTR. Analysis was performed on 19 KTR in Seoul St. Mary's Hospital. All these patients underwent an indication biopsy for reasons such as elevated serum creatinine, proteinuria, and DSA detection. Blood samples were collected immediately before the biopsy and dd-cfDNA test was performed using the AlloSeq cfDNA kit. The biopsy specimen was diagnosed by a renal pathologist according to Banff classification.

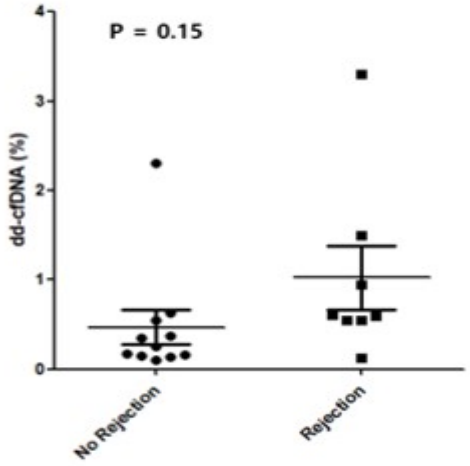
Results: Of the total 19 patients, 8 patients were diagnosed with rejection, and the other 11 patients were diagnosed with glomerulonephritis, acute tubular necrosis, and BK virus nephropathy. The mean titer of dd-cfDNA in patients diagnosed with rejection was 1.02%, which was higher than 0.41% of patients without rejection, but showed no statistical significance (P=0.15).

The median dd-cfDNA in all patients was 0.55%. As a result of comparing the pathologic findings by dividing the group with high and low dd-cfDNA titer based on 0.55%, the g, t, i, ti, and C4d scores were higher in the high dd-cfDNA group. The ah, aah, ct, ci, mm, and IFTA scores were higher in the Low dd-cfDNA group. When comparing the sum of g, ptc, cg, and C4d scores related to antibody-mediated rejection, the high dd-cfDNA group showed significantly higher values (P=0.03). The sum of t, i, v, and cv scores related to T cell mediated rejection also showed a high tendency in the high dd-cfDNA group, but was not statistically significant.

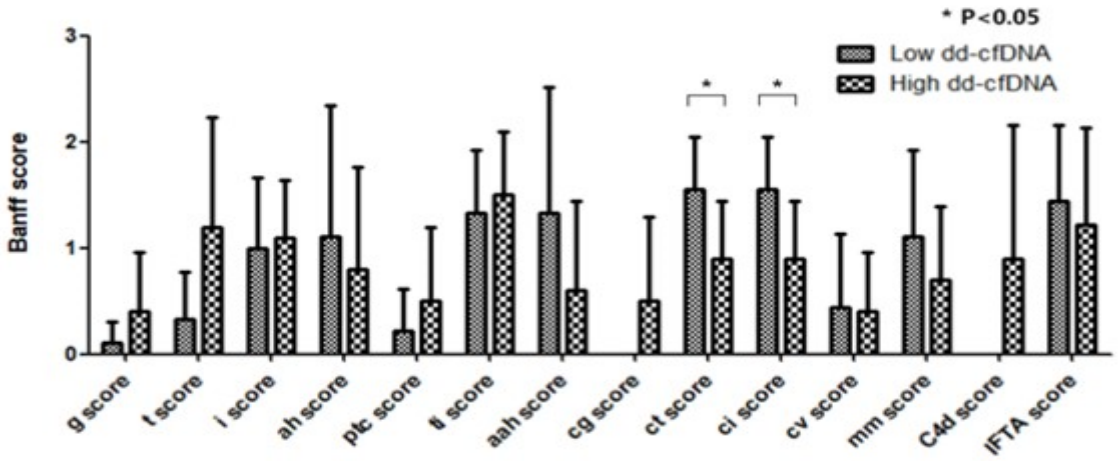
Conclusions: In KTR the dd-cfDNA titer is useful as a predictor of rejection. In particular, the predictive power of renal injury related to antibody-mediated rejection was high.

Figure 1. dd-cfDNA results

(A) Comparison of dd-cfDNA titer between rejection and control group



(B) Comparison of Banff score between high and low dd-cfDNA group



(C) Comparison of Banff score associated with rejection between high and low dd-cfDNA group