VitaGraft Kidney™
Personalized Transplant Monitoring

Clinical Publication Summary

Time-Dependent Apparent Increase in dd-cfDNA Percentage in Clinically Stable Patients Between One and Five Years Following Kidney Transplantation

Schütz E, Asendorf T, Beck J, et al. (2020) Clin Chem 66(10):1290.

Practical Clinical Utility

For long-term surveillance, measurement of absolute dd-cfDNA (cp/mL) concentrations appears to be superior to the fractional abundance of dd-cfDNA (%)

Endpoints and Goals

- **Assess changes in dd-cfDNA (%) reference values by measuring total cfDNA dynamics over several years following kidney transplantation**
- **Determine whether dd-cfDNA (%) is as effective as absolute dd-cfDNA (cp/mL) for long-term graft surveillance**
- **Evaluate a possible relationship between cfDNA and tacrolimus**

Methods

- Single-center, cross-sectional study cohort (part of a prospective clinical validation trial) evaluated **929 plasma samples from 303 clinically stable kidney transplant patients** at nine defined time points from 12 to 60 months following kidney transplantation
- dd-cfDNA (%) and dd-cfDNA (cp/mL) were directly compared along with additional laboratory values from routine monitoring (creatinine, white blood cell count, eGFR, and ISD)

Results

Total cfDNA median values steadily decreased over time among the 303 clinically stable patients during the observation period, resulting in increasing dd-cfDNA (%) that was independent of graft health.

- There was a sustained significant difference in total cfDNA compared to healthy controls (HC) and patients with other medical conditions (OC) not receiving immunosuppression

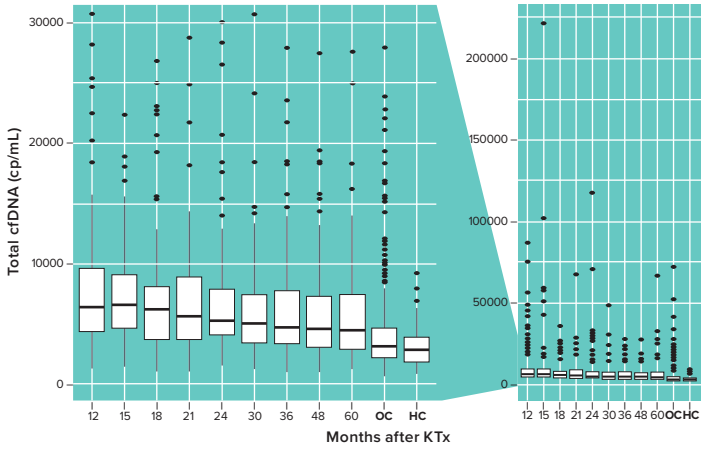

FIGURE 1. Time course of total cell-free DNA (cf-DNA) during the 60 months study period. Boxes depict the 25th and 75th percentiles as a box and a median line; *whiskers extend to minimum or maximum, but at most 1.5 x IQR;* Left side with restricted y-axis; Right side with y-axis covering all outliers.

Absolute dd-cfDNA (cp/mL) was stable during observation period, along with median plasma creatinine and eGFR, confirming that absolute quantification accurately reflected the 303 healthy stable patients.

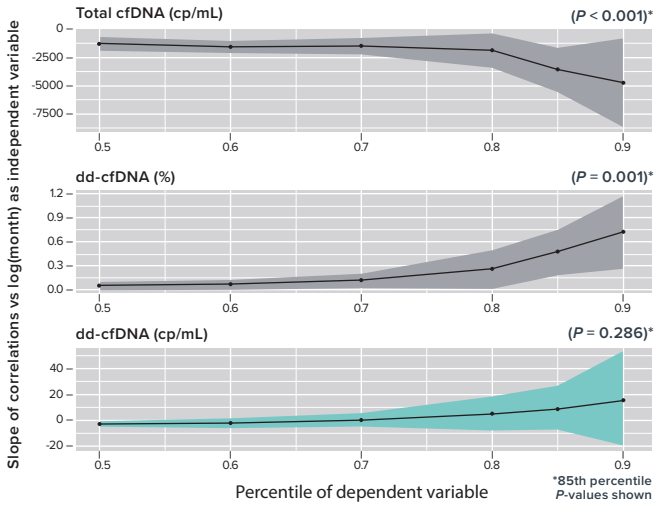

FIGURE 2. Regression analyses of study variables vs log-months after kidney transplant. Time dependencies are given as slope coefficients of quantile regression for given parameters (y-axes) vs log-months for the different percentiles (x-axis). A deviation of the 95%-pointwise confidence intervals (shaded area) from 0 indicates a significant change of values with time. cfDNA: cell-free DNA; dd-cfDNA: donor derived cell-free DNA.

Conclusion

Calcineurin inhibitor (CNI) therapy increased the amount of total cfDNA, which decreased during drug tapering and led to an increase in dd-cfDNA (%). The absolute amount (cp/mL) and the established threshold remained stable.

ONCOCYTE CORPORATION 2 International Plaza, Ste 510 / Nashville, TN 37217 / www.oncocyte.com / info@oncocyte.com / 949.409.7600

ONCOCYTE™ Where Tomorrow LIVES