CASE STUDY

Long-Term Monitoring of Graft Health

Despite rejection continuing to occur for many years post-kidney transplant, the frequency of biopsies performed decreases over time post-transplant. Transplant physicians rely on routine lab tests such as serum creatinine levels to monitor long-term graft health

CASE PROFILE

- 30-year-old female patient
- 3 years post transplant
- Acute cellular rejection (Banff Grade 1a) at 2 years post-transplant. Treatment with pulse steroids improved SCr, no repeat biopsy performed
- Current immunosuppression: tacrolimus and mysophenolate mofetil, steroids were weaned off following ACR treatment

RELEVANT TESTS:

Last month

- Serum Creatinine stable (1.1-1.3 mg/dL)
- One year ago, DSA Negative

GOAL

Surveillance of patient for long term graft health without biopsies

Although your patient is showing no signs of clinical rejection, you have decided to order TruGraf with a 'For Surveillance' Indication

TruGraf Result: Not-TX

At risk for rejection

An elevated serum creatinine (and associated lower GFR calculation) is currently considered an appropriate pre-test considerations to prompt a for-cause biopsy

This patient continues to have a stable serum creatinine, but now has clinical concern for rejection with a positive gene expression

Half of all rejection episodes result in either recurrence or persistence of rejection. Before rejection can manifest as graft dysfunction, it may be observable as subclinical rejection (*Naessans et al. Transplantation 2020*)

The TruGraf result led to a 'for cause' assessment with a dd-cfDNA test

Viracor TRAC: 4.05%

At risk for rejection

The combination of Not-TX result from TruGraf and an at risk for rejection result from Viracor TRAC indicates this patient has a high likelihood of subclinical rejection

- You decide to perform a biomarker prompted biopsy
- Results from the biopsy indicate subclinical mixed rejection
- You treat the rejection with pulse steroids, IVIG, and rituximab

You decide to follow up with a TruGraf test two months post-treatment

TruGraf Result: TX

Low risk for rejection

Conclusion:

Because of these results, early intervention was possible. The combination of surveillance monitoring with TruGraf and for cause testing with TRAC provided insight into your patient's immune activation. These non-invasive results enable a higher confidence in your decision to perform a biopsy for this stable patient.

Molecular biomarkers can provide guidance for treatment along the patient journey, first leading to biomarker-prompted biopsy, indicating subclinical, mixed rejection, then indicating resolution of rejection with a return to negative results.

TRUGRAF® Kidney

MolDX (A58019) Billing and Coding: Intended Use Guidelines
Molecular Testing for Solid Organ Allograft Rejection

eurofins | Transplant Genomics

Test & Manufacturer	Methodology	Specimen Source	Analyte(s) and Principle of Test	Indication / Transplant Type	Intended Use
Surveillance					
TruGraf® Eurofins Transplant Genomics	Gene Expression Profile (GEP) (RT-PCR)	Blood	GEP signatures that identify patients that are adequately immunosuppressed	Kidney	TruGraf® is intended for use in patients with stable renal function to assess immune status as an alternative to surveillance biopsy in kidney transplant patients who are more than 90 days post-transplant.
For Cause					
Viracor TRAC® Eurofins Transplant Genomics	Low-coverage whole genome sequencing (WGS) querying >100,000 SNPs	Blood	% dd-cfDNA is measured to identify graft injury and acute rejection (AR)	Kidney	Viracor TRAC® is intended to assess the probability of allograft rejection in transplant recipients with clinical suspicion of rejection and to inform clinical decision-making about the necessity of biopsy in such patients at least 2 weeks post-transplant in conjunction with standard clinical assessment.
Prospera™ Natera™	mmPCR-NGS targeting 13,926 SNPs	Blood	% dd-cfDNA is measured to identify graft injury and acute rejection (AR)	Kidney	Prospera™ is intended to supplement clinical evaluation and management of AR in patients who have undergone renal transplantation. The test discriminates AR (vs no-AR) and may assist with ruling in or out this condition when assessing the need for or results of a diagnostic biopsy.
AlloSure® Kidney Care Dx®	NGS (targeting 266 SNPs)	Blood	% dd-cfDNA is measured to identify graft injury and acute rejection (AR)	Kidney	AlloSure® Kidney assesses the probability of AR in kidney transplant recipients with clinical suspicion of rejection and informs clinical decision-making about the necessity of renal biopsy in such patients at least 2 weeks post-transplant in conjunction with standard clinical assessment.

AR = acute rejection ; dd-cfDNA = donor-derived cell-free DNA ; GEP = gene-expression profile; mmPCR = massively multiplexed polymerase chain reaction ; NGS = next generation sequencing; RT-PCR = reverse transcription polymerase chain reaction; SNPs = single nucleotide polymorphisms; WGS = whole genome sequencing

Learn more at transplantgenomics.com

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