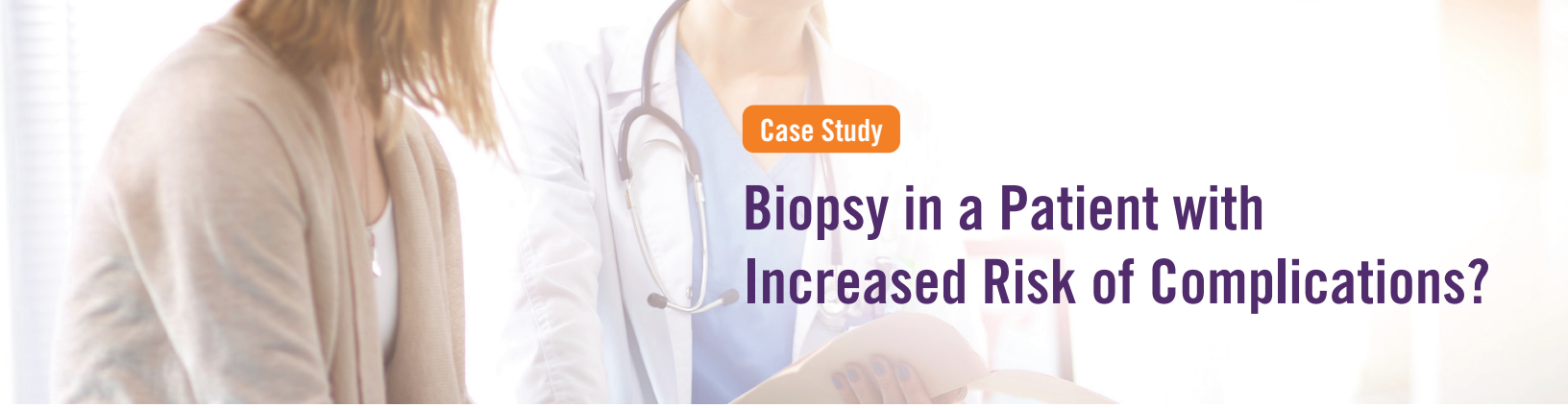

Case Study

Biopsy in a Patient with Increased Risk of Complications?

- 40-year-old female patient
- 2 years post-transplant
- Stable serum creatinine (1.3-1.5 baseline)
- Immunosuppression: tacrolimus and mycophenolate mofetil
- Re-transplant due to thrombosis; on chronic anticoagulation

Goal

Provide additional laboratory confirmation that biopsy is necessary in a complicated or high-risk biopsy patient.

Approach

Closely monitor immune status of patients with OmniGraf and utilize results with other clinical findings to make biopsy decisions.

Results

OmniGraf confirmed increased risk for rejection with other clinical factors, leading to biopsy showing rejection.

The Challenge with Transplant Patients on Anticoagulation

When clinicians have suspicion for rejection, anticoagulation presents a challenge relating to increased risk of complications during and post biopsy. To decrease the number of unnecessary biopsies in complicated patients, the OmniGraf dual-biomarker (TruGraf gene expression profiling (GEP) and Viracor TRAC donor-derived cell-free DNA (dd-cfDNA)) rejection panel may be useful with other clinical findings to strengthen or weaken the need for a biopsy to minimize invasive procedures.

Case Study: 40-Year-Old Kidney Recipient

This kidney transplant recipient is a 40-year-old female patient, who received her kidney graft two years ago. With stable renal function, OmniGraf was performed:

Month 6 post-transplant:

- TruGraf: Negative / TX (“Transplant eXcellence”): low risk of rejection
- Viracor TRAC: 0.54%, low risk of rejection

Month 8 post-transplant:

- TruGraf: Positive / Not-TX: at risk of rejection
- Viracor TRAC: 0.6%: low risk of rejection

Month 9 post-transplant:

- TruGraf: Positive / Not-TX: at risk of rejection
- Viracor TRAC: 0.43%: low risk of rejection

Monitoring the Effects of Medication Changes with OmniGraf

OmniGraf Kidney is a non-invasive panel of two novel biomarkers; it is the only combination panel available today that offers the earliest possible detection of “silent” subclinical acute rejection. It is a powerful tool to use in quickly assessing the adequacy of immunosuppression regimens.

OmniGraf Results Contribute to Decision to Biopsy Complicated Patient

Following the two positive TruGraf tests, the clinician decided to proceed with a for-cause biopsy in the high-risk anti-coagulated patient. The biopsy findings revealed “borderline subclinical acute cellular rejection.”

In this case, OmniGraf, along with other clinical factors, supported the decision to perform a biopsy on a high-risk patient despite the logistical challenges. Without OmniGraf alerting the clinician to possible subclinical rejection, the patient may have progressed to clinical acute rejection with possible progressive loss of kidney function.

OMNIGRAF™

The first and only non-invasive panel that combines genetic biomarker tests for the earliest and most accurate view of kidney transplant rejection.

	Combination Panel	Gene Expression	Donor-Derived Cell-Free DNA
	OmniGraf™	**TruGraf®**	**Viracor TRAC®**
Type of Biomarker	Blood gene expression (120 genes) & dd-cdDNA (~100,000 SNPs)	Blood gene expression (120 genes)	dd-cfDNA (~100,000 SNPs)
Context of Use	Earliest[1] and most accurate[2] detection of subclinical and clinical rejection in transplant patients with stable kidney function	Rules out subclinical rejection in kidney transplant recipients with stable kidney function	Rules out acute rejection in kidney transplant recipients with suspicion of clinical acute rejection
Validation	Surveillance	Surveillance	For-cause biopsy
When to Start Testing	90 days post-transplant	90 days post-transplant	Suspicion of clinical rejection
Blood Draw Required	6ml / 1 tube	5ml / 2 tubes	10ml / 1 tube
Result Measurements	Gene Expression (***TruGraf***): TX (Transplant eXcellence) or Not-TX dd-cfDNA (***Viracor TRAC***): % of dd-cfDNA	TX or Not-TX	% of dd-cfDNA
Interpretation of Results	Negative / TX & <0.7 = low risk of rejection Positive / Not-TX & ≥0.7 = high risk of rejection	Negative / TX: low risk of rejection Positive / Not-TX: at risk of rejection	< 0.7% clinical rejection unlikely ≥ 0.7% clinical rejection should be considered
Negative Predictive Value (NPV)	94%	92%	92%
Positive Predictive Value (PPV)	89%	65%	40%
Suggested Testing Frequency	Quarterly monitoring	Quarterly monitoring	Clinical suspicion of rejection
Rejection Type Targeted	TCMR & ABMR	TCMR	ABMR

[1]OmniGraf and TruGraf are the only tests that detect subclinical acute rejection, before the onset of clinical acute rejection.
[2] OmniGraf has the highest Positive Predictive Value of currently-available biomarker-based rejection tests.

Learn more at
transplantgenomics.com/omnigraf-kidney

@EurofinsTGI

eurofins | Transplant Genomics

Jan 2022