ABSTRACT BIOTRAIM STUDY WTC 2025

Title: Pretransplant Response to Immunosuppressants Measured with Immunobiogram Predicts First-Year Rejection in Kidney Transplant Recipients

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Study's purpose: To evaluate whether in vitro response to immunosuppressive drugs (IMS) measured with Immunobiogram (IMBG) pretransplant predicts first-year rejection in kidney transplant (KT) patients.

Methods: BIOTRAIM is an observational, multicenter, longitudinal study in KT to assess the association of pretransplant IMBG results and first-year Biopsy Proven Acute Rejection (BPAR) events, including one-year per-protocol biopsy. IMBG examines isolated and stimulated patient PBMCs in 3D-cell cultures exposed to individual IMS concentration gradients along the channels of a plate. PBMCs activation/proliferation determines the response to mycophenolate, tacrolimus, sirolimus, everolimus and corticosteroids. Results are translated into dose-response curves and calculated negative Z-Scores indicate a lack of individual IMS sensitivity related to a reference population.

Results: From 107 patients included with a valid IMBG pretransplant, 24 patients presented BPAR. Based on multiple logistic regression, less negative Sums of Z-Scores are associated with lower risks of BPAR with an OR=0.40, 95% CI (0.18-0.91), p=0.028, adjusted to risk levels based on classical prognostic factors and a cumulative incidence of rejection of 20% (Table 1, Figure 1).

Conclusions: IMBG measures in vitro the pharmacodynamic response to immunosuppressive drugs in KT patients. Pretransplant IMBG significantly increases the ability to predict rejection in the first-year post-transplant in addition to traditional prognostic risk factors.

Table 1. Probability of rejection by levels of immunological risk and IMBG Sum of negative Z-Scores

Immunological Risk	IMBG Sum_ZS_neg	Rejection Probability	Immunological Risk	IMBG Sum_ZS_neg	Rejection Probability	Immunological Risk	IMBG Sum_ZS_neg	Rejection Probability
Low	-5	46.6%	**Medium**	-5	89.1%	**High**	-5	98.6%
Low	-4	25.9%	**Medium**	-4	76.5%	**High**	-4	96.6%
Low	-3	12.3%	**Medium**	-3	56.7%	**High**	-3	92.0%
Low	-2	5.3%	**Medium**	-2	34.4%	**High**	-2	82.2%
Low	-1	2.2%	**Medium**	-1	17.3%	**High**	-1	64.9%
Low	0	0.9%	**Medium**	0	7.7%	**High**	0	42.6%

Figure 1. Contribution of IMBG in addition to clinical factors: more negative Z-scores increase risk of rejection