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Title: First Year Pre-transplant Immunobiogram (IMBG) Predictability of de novo Rejection or Infection after 3 months in Biotraim Study

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Purpose: to evaluate the in vitro response to immunosuppressive drugs (IMS) measured with IMBG Pre-transplant (TX) and predict first-year de novo rejection or infection occurring after 3 months in kidney TX patients.

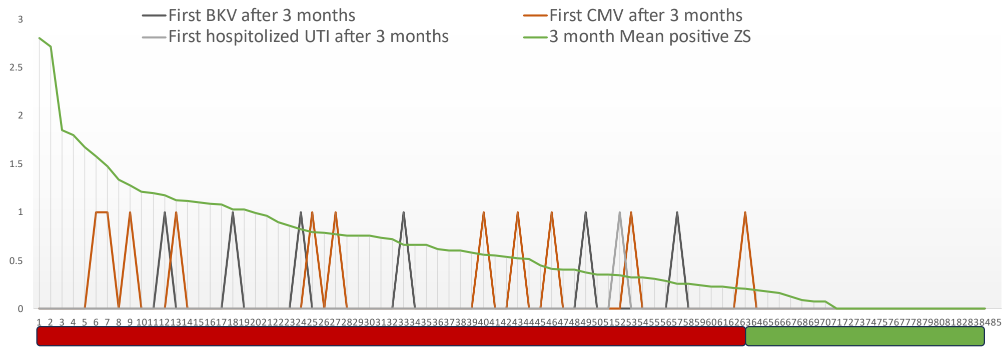
Methods: IMBG examines isolated/stimulated PBMCs in cultures with individual IMS concentration gradients of mycophenolate, tacrolimus, sirolimus, everolimus, and corticosteroids to assess efficacy in vitro. Results built patient-specific dose-response curves, calculated into negative or positive Z-Scores indicating reduced or increase individual IMS sensitivity related to a reference population. We evaluated IMBG in an observational, multicenter, longitudinal kidney TX study-BIOTRAIM. We report the association of Pre-TX IMBG Z-scores in a subgroup of patients evaluated for de novo rejection or infection after 3 months. IMBG negative or positive scores were correlated to rejection or infection, respectively, using only IMBG reported sensitivities to medications prescribed at 3 months.

Results: of 107 patients with Pre-TX IMBG, 92 had 3-month IMS data and no rejection at/prior to the 3-month visit. Of these 92, all 14 patients with a de novo rejection after 3 months had a mean negative Z-score <-0.187. No patients with a mean negative Z-score >-0.187 (n=28) suffered acute rejection. Then, we analyzed the 84 patients who had 3-month IMS data and no infection at/prior to the 3-month visit. Of these, all 18 patients with a de novo infection after 3 months had a mean positive Z-score >0.206. No patients with a mean positive Z-score <0.206 (n=21) suffered infections.

Conclusions: Pre-TX IMBG significantly improved detection of patients at risk for rejection or infection. Tailoring use to center-specific rates with IMBG may lower the overall event rate or identify patients for reduction of IMS.

BIOTRAIM Clinical Study (Pretransplant IMBG N=84)

Comparison of IMBG Positive Z -Scores for prescribed 3 -month IMS to first Infections after 3 months

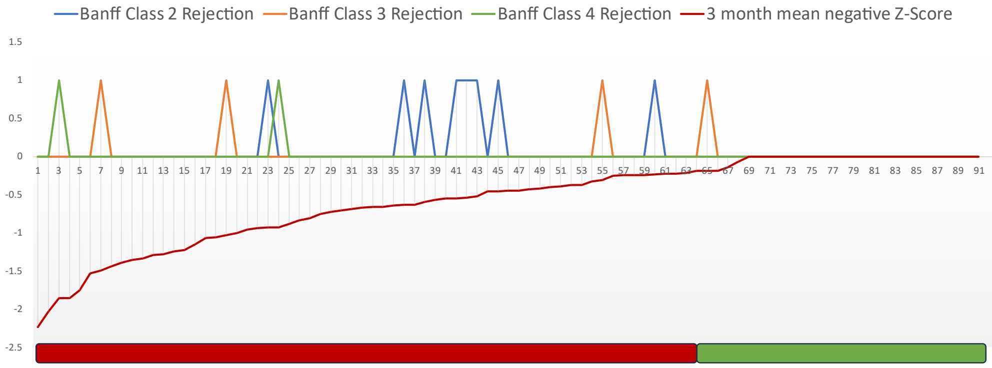


Mean Positive Z-Score >.206 <u>with</u> first Infection after 3 months
n=18/63

Mean Positive Z-Score <.206 <u>with</u> first Infection after 3 months
N=0/21

BIOTRAIM Clinical Study (Pretransplant IMBG N=91)

Comparison of IMBG negative Z -Scores for prescribed 3 -month IMS to first rejections after 3 - months



Mean negative Z-Score <-0.187 <u>with</u> first Rejection after 3 months
n=14/65

Mean negative Z-Score >-0.187 <u>with</u> first rejection after 3 months
N=0/26