Non-invasive MR Imaging Diagnosis of Transplant Rejection

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Statistical Analysis Plan

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Statistical Analysis Plan

Histopathology

Patients with allografts underwent routine biopsies either on the same day as the MRI, before the MRI, or after the MRI. The biopsy specimens were dissected parasagittally, kept in formalin overnight, dehydrated through graded alcohol washes (70, 95, and 100 %), embedded in paraffin and sliced on a microtome. Five-micrometer thick tissue slices on glass slides were stained with hematoxylin and eosin (HE) and Periodic acid-Schiff (PAS) stains. In addition, the samples were stained with antisera against CD163 (Novocastra, Clone 10D6, 1:50 dilution, performed on the Ventana XT using HIER solution CC1, pH 8.0). The histological and immunohistochemical analysis was performed under a light microscope (Olympus BX51). The biopsy samples were evaluated for cellular and antibody-mediated rejection as per the Banff 2013 criteria. Evidence for other disease processes affecting the allograft was also sought. The CD163 stained slides were scored blinded as follows: no stained cells = 0, G10 positive cells/hpf present in G25 % of biopsy = 1, 910 positive cells/hpf in 26–50 % of biopsy = 2, and 910 positive cells in 950 % of biopsy = 3.

Data Analysis

GFR and MRI data were compared between patients with non-rejecting and rejecting allografts using the two-sided t test. In addition, mean T2* values of whole kidneys as well as kidney cortex and medulla were compared between the three patient groups of native, non-rejecting and rejecting allografts using analysis of variance (ANOVA). In addition, T2* relaxation times were correlated with the CD163 score, using a linear regression analysis. All statistical computations were performed with Microsoft Excel software. An alpha level of 0.05 was chosen to indicate significant differences.