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FURTHER ANALYSIS OF THE INTRAVASCULAR ULTRASOUND DATA FROM THE RANDOMIZED MYCOPHENOLATE MOFETIL (MMF) TRIAL IN HEART TRANSPLANT RECIPIENTS

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First year intravascular ultrasound (IVUS) measurements, including the change from baseline to 1-year maximal intimal thickness (MIT) greater than 0.5mm, have been recently reported to be a surrogate marker for long-term outcome after heart transplantation. This IVUS measurement most likely represents a heightened immune response of the recipient to the donor heart, which can lead to allograft vasculopathy and subsequent poor outcome. First year IVUS data can be analyzed by site-to-site analysis (recent reports) or by morphometric analysis (average of 10 sites, without matching sites which was done in the MMF Trial) in the same coronary artery from baseline to 1-year. Since intimal thickness is heterogeneous with most sites having little or no intimal thickening, morphometric analysis will not be sensitive to detect changes at any one particular site as it averages data from multiple (usually 10) sites. In this regard, morphometric analysis of the first year MMF IVUS data may not have accurately depicted the impact of MMF on first year MIT in the study patients. MMF has been reported to decrease intimal thickening in animal transplant models. The MMF trial involved 650 heart transplant patients from 28 centers to receive MMF (3000 mg/day) or azathioprine (1.5–3.0 mg/kg/day), in addition to cyclosporine and corticosteroids. Baseline and 1-year IVUS were performed in 196 patients (102 MMF and 94 azathioprine patients) with no differences in IVUS results by morphometric analysis found between the study groups. Further analysis of the IVUS data using site-to-site analysis from baseline to 1-year will be performed at the Core IVUS Laboratory. The number of patients with change in MIT greater than 0.5mm from baseline to 1-year at any one site will be determined for MMF-treated patients compared to azathioprine-treated patients. Results of this analysis will be presented at the ISHLT Scientific Sessions 2004.
