Clinical Utility of Cylex: Conversion to Everolimus Immunosuppression in Heart Transplant Recipients

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Background: The Cylex ImmuKnow assay is a test of immune response used to identify solid organ transplant recipients at risk for either acute rejection or infection. Everolimus, a relatively new Immunosuppressant (IS) agent has improved tailoring the optimal IS regimen for the individual heart transplant (HTx) recipient. Empirical dosing of the different IS drugs when changing IS protocols bears the risk of either under or over immunosuppression. In the present study we assessed the safety of the conversion to Everolimus based immunosuppression (EBI) in HTx recipients using the Cylex assay.

Methods: The clinical course of all the HTx recipients converted to EBI (n=36) at our center from the introduction of the Cylex assay (July 2007) was examined. Everolimus doses were altered according to the Cylex levels aiming at the quiescence levels. The rate of rejection and infection occurring during the first 3 months post conversion to EBI were compared with the rate of those events at the EBI maintenance period.

Results: Everolimus levels in the CNI free and reduced protocols were 6.1±2.5 and 4.8±2 respectively. Cyclosporine and FK levels were 66±21.1 and 4.2±2.5 respectively. Mean±SD Cylex levels pre conversion, 3 months post conversion and at the maintenance period were 365±181 (range 33-940), 355±120 (range 44-888) and 329±148 (range 48-600) ng/ml ATP respectively (p=NS). There were 2 infections and one rejection vs. 13 infections and 5 rejections during the first 3 months post conversion to EBI vs. the maintenance period (1.8% and 0.9% vs. 2.1% and 0.8% per patient month, P=NS).

Conclusions: The Cylex ImmuKnow assay has the potential to assist in the tailoring of the most safe and efficient IS therapy for each HTx recipient.