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Title: Early sirolimus immunosuppression is safe in lung transplantation

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Body: BACKGROUND: Sirolimus based immunosuppression administered de-novo after LTx has been shown to be associated with bronchial anastomosis healing complications. We hypothesized that, in select LTx recipients, sirolimus due to its antiproliferative properties and minimal side effect profile when began within the first post-operative month is safe and associated with a favourable short and long term outcome. MATERIALS AND METHODS: Between December 2004 and October 2011, 62 LTx were performed at a single institution. Ten patients (16.1%) mean age 46.9 ± 11.9 years old were selected to received early sirolimus based immunosuppression regime along with cyclosporine and prednisone with all receiving induction immunosuppression. Patients were selected to receive early sirolimus based on an uncomplicated post-operative course and decisively after bronchoscopic assessment. RESULTS: Sirolimus was begun on mean POD 20.5 ± 5.4 (14-32). In-hospital / 30-day mortality was 0%. On long-term follow up 3 patients died, 2 due to bacterial infection and in one patient PCP infection. Mean survival was 3.6 ± 1.9 years (1.1 - 6.9), 1-year survival was 90% and 5-year survival was 75%. In 4 patients (40%) sirolimus was stopped, in 3 due to infection and in one because of re-transplant. None of the patients displayed BOS based on FEV1. In the patients still taking sirolimus renal function was within normal range. The study patients did not suffer increased rate of bacterial, PCP or CMV infection when compared to standard immunosuppression patients. CONCLUSION: Contradictive to previously published studies, our results show that early sirolimus based immunosuppression is safe and is associated with a beneficial side-effect profile.