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Title: Aerosolized liposomal cyclosporine A for treatment of progressive allograft dysfunction following lung transplantation

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Body: Aim: The aim of this study was to evaluate aerosolized liposomal cyclosporine a (LCsA) in lung transplant recipients (LTR) with progressive chronic lung allograft dysfunction (CLAD) after failure of conventional therapy (pulsed steroids, azithromycine, montelucast, extracorporeal photophoresis). Methods: Descriptive data analysis was performed prospectively based on lung function testing. Results: 6 LTR (age 38±11.8 years; 3 male; 4 DLTx; 2 HLTx; 5.7±5.1 years after Tx, BOS 1 n=1; BOS 2 n=1; BOS 3 n=4) received LCsA 10mg twice daily p.i. for 50 days (4-365d) as add-on therapy to tacolimus, mycophenolate mofetil and steroids. Two patients inhaled < one week due to re-Tx and cough/nausea and were excluded from analysis. Of the remaining 4 patients baseline FEV1, FVC and TLC were 1.11±0.21I (34±14%pred.), 1.8±0.4l (51±26%pred.) and 4.53±0.8l (76±19%pred.). Interims analysis after 43±29 days revealed a FEV1 of 1.1±0.5l (34±13%pred.), a FVC of 1.75±0.85l (50±21%pred.) and a TLC of 4.35±0.5l (72±22%pred.) and after 107±122 days a FEV1 of 0.81±0.32l (31±14%pred.), a FVC of 1.52±0.68l (47±25%pred.) and a TLC of 4.26±0.67I (74±25%pred.). Laboratory evaluations showed no systemic LCsA concentration (<30ng/ml), no significant change of creatinine levels and no positive CMV-PCR. One patient died (219d), one patient was re-transplanted (43d) and one patient stopped due to pulmonary infections (57d). Conclusion: This case series of selected, treatment-resistant CLAD patients suggest that the use of LCsA in LTR is safe. The therapeutic potential of LCsA in LTR with CLAD should be investigated in future controlled trials. eFlow® device and LCsA was provided by PARI Pharma GmbH.