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**Title:** BAL neutrophil levels in a randomised controlled trial of azithromycin therapy in bronchiolitis obliterans syndrome post lung transplantation

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**Body:** Open studies have reported an improvement in FEV1 in some BOS patients treated with Azithromycin (Azith). We recently demonstrated that Azith is superior to placebo treatment, improving FEV1 in patients with BOS. It is suggested that a BAL neutrophil reduction is associated with treatment benefit. We have investigated this in our trial. Methods: A prospective, randomised double blind placebo controlled study of Azith 250mg o.d. or placebo on alternate days, in BOS patients. The primary outcome was change in FEV1 at 12 weeks and a secondary outcome BAL neutrophil %. Results: 46 patients were randomised (23 Azith, 23 placebo) stratified for pre op diagnosis of suppurative disease and operation (single or bilateral lungs). Of the 46 ITT patients, baseline and final visit BAL were available for 28 (13A, 15P). In these patients the baseline % neutrophils, median (IQR), in the Azith group was 17 (4 to 69%) and in the placebo group 15 (2 to 56%). The baseline to final visit change in % neutrophils varied, with around half the patients in both treatment arms showing an increase from baseline and half a decrease. There was a median increase from baseline in the Azith group of 10%, IQR (—10% to 18%) and in the placebo group a median decrease from baseline of —1% (—8% to 5%). These changes were statistically non significant (P=0.4 and 0.7 respectively, 1-sample Wilcoxon). Conclusion: Azith is superior to placebo improving lung function in patients with BOS. In the same patients, whilst BAL neutrophil % was high, we observed no consistent fall with Azith. This may suggest the mechanism of benefit does not rely on a quantitative reduction in neutrophils.