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Title: 6 and 12 month outcomes following RePneu bronchoscopic lung volume reduction coil treatment

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Body: ZZ and SK contributed equally INTRODUCTION: The RePneu Lung Volume Reduction Coils (LVRCs) are nitinol devices implanted bronchoscopically using fluoroscopic guidance, and retake their original coiled shape as they are deployed. Around 10 LVRCs implanted in an emphysematous lobe reduce hyperinflation and gas trapping. METHODS: The RESET trial randomised 23 emphysematous subjects with severe airflow obstruction and hyperinflation to LVRC treatment and 23 to best medical care (controls). LVRC treatments were unilateral and sequential with a 1 month interval between treatments. Assessments of lung function, 6 minute walk distance (6MWD) and St. George's Respiratory Questionnaire (SGRQ) occurred at baseline, 3, 6 and 12 months following the final treatment. The 3 month primary endpoint results (previously reported) showed significant improvements in outcomes in the LVRC group compared to controls. Controls joined the treatment group and had LVRC treatment after completion of the control phase. NCT01334307. RESULTS: 39 patients completed 6 months follow-up and had reduction in SGRQ (-7.1 points, p=0.0004), increase in 6MWD(56.3 m, p<0.0001), increase in FEV1 (14.3%, p<0.0001), and reduction in the residual volume (RV)(-0.41 litres, p=0.0007). The benefits in SGRQ (-10.0, p<0.0001), 6MWD (49.8, p=0.0002) and FEV1 (10.2%, p=0.03) persist in the 24 patients who have completed 12 months follow-up. 6 and 12 month follow-up data for the entire cohort (n=46) will be presented at the ERS conference in September 2013. CONCLUSION: Statistically and clinically meaningful benefits in quality of life, exercise capacity and pulmonary function in patients treated with LVRC coils persist 12 months after treatment.