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Title: Validation of multiple breath washout technology in healthy children and children with CF

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Body: Mass spectrometry based technology is considered the “gold standard” for measuring LC, but is not readily available. In this ongoing study we aim to validate a nitrogen washout system for use in CF children. In a cross-over design, healthy and clinically stable CF children performed MBW by mass spectrometry (AMIS 2000; Innovision A/S, Odense, Denmark) using 4% SF₆ or by nitrogen washout (Exhalyzer D, Eco Medics AG, Switzerland). Results were independently scored by two operators; Bland-Altman plots were used to assess the agreement between the two systems. To date 24 healthy children (median age 11 years (range 3-17)) and 33 children with CF (median age 11 years (range 3-17) completed MBW measurements using both the mass spectrometry and N₂ washout. There was no systematic bias observed in LCI between the two methods. Overall there was good agreement healthy children (95% of all measurements agreed within -0.44; 0.83); however LCI_{SF₆} was systematically 0.2 (95% CI 0.06; 0.33) units lower than LCI_{N₂}. The mean difference between the two systems was greater in children with CF (0.4 (CI 0.29 to 0.55) and the limits of agreement were wider (-0.33; 1.17). Agreement between the two methods for moment ratios was better for the M1M0 (-0.43; 0.63) than M2M0 (-5.72; 8.60), and greater in healthy children compared with children with CF. Inter-observer agreement for nitrogen washout was high (-0.08; 0.08) for all outcomes. These data suggest that while there is no systematic bias between the two systems, LCI measured by nitrogen washout is higher compared to LCI measured by mass spectrometry. Inter-observer variability is low for nitrogen washout if analyzed by trained operators. Supported by CFF.