

Validation of an ultrasonic device for routine use of the nitrogen washout technique

Susanne I Fuchs¹, Christian Buess², Edmund Petri³, Georg Hülskamp³, Monika Gappa¹

¹Marien Hospital Wesel GgmbH, Childrens Hospital and Research Institute, GERMANY, ²ndd Medical Technologies, Zurich, SWITZERLAND, ³Clemenshospital GmbH Münster, Childrens Hospital, GERMANY

INTRODUCTION

We have previously reported successful validation of an ultrasonic prototype device for assessing ventilation inhomogeneity and particularly the Lung Clearance Index (LCI) using Multiple Breath Washout with 4% Sulfurhexafluoride (MBW_{SF6}) including a multicenter feasibility study. However, routine use of MBW_{SF6} is limited because of the green house effect of SF₆, the extended test duration and because SF₆ is not licensed as medical gas in most countries. Nitrogen washout (MBW_{N2}) using 100% oxygen therefore is an attractive alternative. Consequently, the prototype equipment has been adapted for use with 100% oxygen and has recently been implemented into an existing lung function device (EasyOne Pro LAB™, ndd Switzerland), with the aim to facilitate application of MBW_{N2} for clinical routine.

AIM

The aim of the present validation study was

1. to compare MBW_{SF6} (prototype device) with MBW_{N2a} (prototype device) and
2. to compare MBW_{N2a} (prototype device) with MBW_{N2b} (EasyOne Pro LAB™).

METHOD

Subsequent MBW_{SF6}, MBW_{N2a} and MBW_{N2b} were performed in randomised order and during one test occasion in healthy volunteers. 2-3 single washouts were required for each of the three methods.

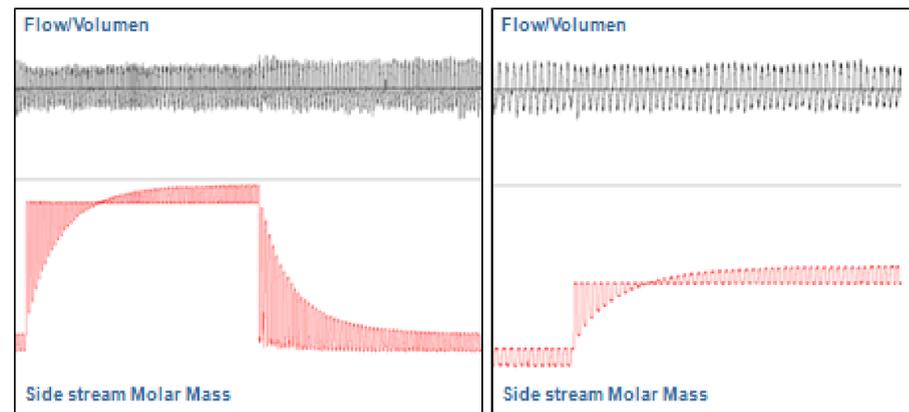
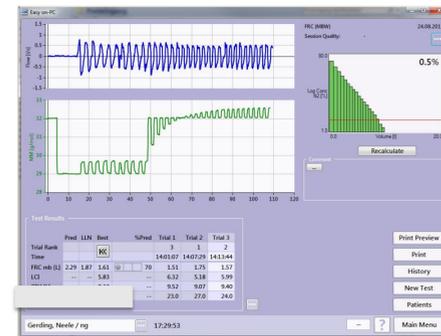


Figure 1: MBW_{SF6} MBW screenshot using the prototype device, requiring manual analysis and longer test duration due to use of SF₆ and multiple use accessories (disinfection between subsequent patients)

Figure 2: MBW_{N2a} MBW screenshot using the prototype device, requiring manual analysis and longer test duration due to use of SF₆ and multiple use accessories (disinfection between subsequent patients)



Figures 3 and 4: MBW_{N2b} with EasyOne Pro LAB™ and corresponding screenshot with real time traces of flow and molar mass and automated analysis

RESULTS

17 healthy volunteers (7-51years) were recruited for the study.

Mean LCI_{SF6} (SD) was 6.77 (0.53), mean LCI_{N2a} (SD) was 6.54(0.53) and mean LCI_{N2b} (SD) was 6.56 (0,76).

Mean difference (95% C.I., p-value) between LCI_{SF6} and LCI_{N2a} was 0.21 (-0.13;0.55, 0.210). Mean difference between LCI_{N2a} and LCI_{N2b} was 0.03 (-0.39;0.32, 0.839).

Within-test repeatability of the LCI ranged between 5-6% for each of the three methods.

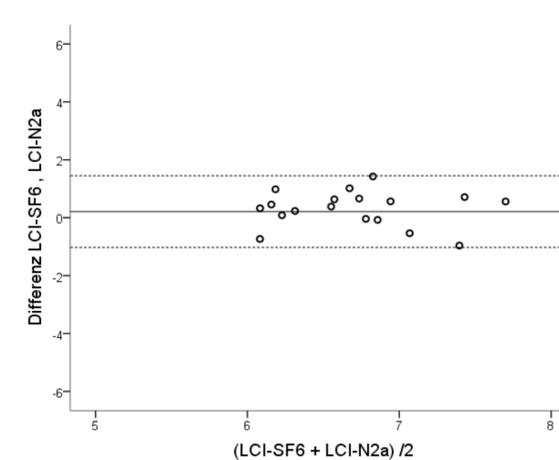


Figure 5: Agreement between individual LCI results for MBW_{SF6} and MBW_{N2a}

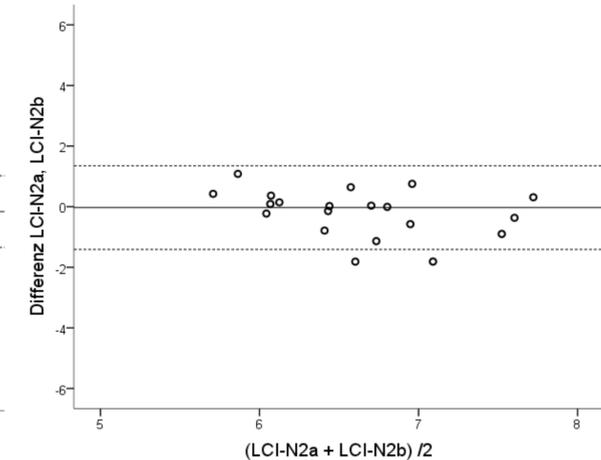


Figure 6: Agreement between individual LCI results for MBW_{N2a} and MBW_{N2b}

CONCLUSION

Nitrogen washout for assessing ventilation inhomogeneity and the LCI using commercially available equipment (EasyOne Pro LAB™) is feasible and yields results similar to those obtained with the preceding prototype device using either SF6 or N2. Handling the new device was very easy using 100% O₂ and single use accessories for hygienic safety. The EasyOne Pro LAB is suitable for measuring the LCI in clinical routine.