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Comparison of Pneumotachometer and Portable Digital Turbine Spirometry for Field-Based Assessment: An Air Quality, Environment, and Respiratory Outcomes in Bronchopulmonary Dysplasia Study

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Introduction: Data on the use of remote spirometry are limited in the pediatric population. We sought to assess the feasibility and accuracy of a digital turbine spirometer, Medical International Research (MIR) Spirobank Smart (MIR, New Berlin, WI, USA), compared with a pneumotachography spirometer, Pneumotrac (Vitalograph Inc., Lenexa, KS, USA), in field-based clinical research.

Methods: This is a cross-sectional study of a subgroup of school-aged participants enrolled in the Air quality, Environment, and Respiratory Outcomes in Bronchopulmonary Dysplasia (BPD) study, who performed same-day paired coached baseline spirometry measurements from the Pneumotrac and MIR devices. Proportion of successful tests was estimated for each device and compared using McNemar's test. Correlation between devices forced expiratory volume in 1 second (FEV₁) and forced vital capacity (FVC) was analyzed by Lin's concordance correlation, and Bland–Altman plots were generated.

Results: Twenty-one participants with history of BPD completed home spirometry maneuvers on both devices. The mean age of participants was 8.7 years. The mean FEV₁ and FVC measurement was 81% predicted and 90.4% predicted, respectively. The proportion of acceptable tests appeared higher using Pneumotrac (81%) than when using MIR (67%), although without evidence of discordance ($P=0.317$). Among subjects with successful tests on both devices, Lin's concordance correlation demonstrated moderate agreement (FEV₁ $r=0.955$, 95% confidence interval [CI]: 0.87–0.98; FVC $r=0.971$, CI: 0.91–0.99). The mean difference in FEV₁ between Pneumotrac and MIR was 0.079 L (95% limits of agreement were –0.141 to 0.298 L) and FVC was 0.075 L (95% limits of agreement were –0.171 to 0.322 L). These were relatively small and without evidence of systematic or volume-dependent bias.

Conclusions: Utilizing turbine spirometers may be a promising and feasible way to perform pulmonary function testing for field research in children.

Keywords: bronchopulmonary dysplasia, COVID-19, pediatrics, remote spirometry

Introduction

OWING TO THE CORONAVIRUS DISEASE (COVID-19) pandemic restrictions on clinical research, a rapid shift to remote spirometry provided continued lung function

assessment for pediatric lung disease trials. Pneumotachography spirometry has most commonly been used for field use in home- and school-based studies, but requires daily calibration, trained staff to administer, and close contact with participants. A new generation of remote spirometers

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based on turbine airflow measurement has emerged with no need for daily calibration and participant self-administration of the test with virtual or remote instruction.

However, little is known about the comparability of a portable turbine-based spirometer, Medical International Research (MIR) Spirobank Smart spirometer (MIR, New Berlin, WI, USA), with the more traditional pneumotachography method, Pneumotrac (Vitalograph Inc., Lenexa, KS, USA), for home lung function assessments in children. Therefore, in our ongoing study of home environmental exposures on respiratory health in school-aged children with bronchopulmonary dysplasia (BPD), we aimed to assess the feasibility and accuracy of the MIR spirometer in field-based clinical research compared with that of a Pneumotrac spirometer. We hypothesized that both devices would yield comparable lung function measurements for field-based use.

Methods

This is a cross-sectional analysis of a subgroup of participants who performed same-day paired spirometric maneuvers from 2021 to 2022 using both Pneumotrac and MIR spirometers in the ongoing single-center prospective observational NIH-funded clinical research cohort enrolled in the Air quality, Environment, and Respiratory Outcomes in BPD study (Clinicaltrials.gov Identifier: NCT04107701). Informed consent/assent was obtained from parents/participants before study procedures.

School-aged children between 6 and 12 years of age who were born <32 weeks gestation with a diagnosis of BPD, defined as the need for supplemental oxygen or other respiratory support in the neonatal period for >28 days, were recruited. Detailed methods have been published previously.¹ Spirometric maneuvers were conducted using both spirometric devices on the same day during a home visit. Participants were excluded if they had a recent or current respiratory tract infection, hemoptysis, or pneumothorax.

Participants were first instructed to perform prebronchodilator spirometry using the Pneumotrac portable spirometer, immediately, followed by the MIR spirometer, an app-based handheld turbine spirometer, with data recorded in an online results dashboard. Both maneuvers were coached in person by trained clinical research staff. Each participant performed a maximum of 6 attempts using each spirometric device. Same-day paired measurements completed by each participant were analyzed. Demographics and baseline characteristics were summarized with standard descriptive statistics. Session quality was graded per 2019 American Thoracic Society (ATS)/European Respiratory Society (ERS) guidelines² and deemed successful if graded A–C.

Proportion of successful tests was estimated for each device and compared using McNemar's test. Correlation between devices forced expiratory volume in one second (FEV₁) and forced vital capacity (FVC) absolute values was analyzed by Lin's concordance correlation, and Bland–Altman plots were generated. The Global Lung Function Initiative (GLI) reference values³ were used in descriptive presentation of percentage predicted lung function.

Results

Of the 104 participants with a history of BPD who were enrolled in the study, 21 participants completed home spirometry maneuvers on both the Pneumotrac and MIR devi-

ces. The average age of participants was 8.7 years. There were 43% of subjects who had a concurrent asthma diagnosis, determined by answering “yes” to being diagnosed with asthma by a physician/nurse. Demographics and baseline characteristics are summarized in Table 1. The mean FEV₁ and FVC measurements obtained from the Pneumotrac device were 81% predicted (standard deviation [SD] 18.14%) and 90.4% predicted (SD 9.0%), respectively, based on GLI reference values.

For the Pneumotrac spirometer, 20 (95%) and 17 (81%) participants performed acceptable maneuvers for FEV₁ and FVC, respectively. As for the MIR spirometer, 17 (81%) and 16 (76%) participants performed acceptable maneuvers for FEV₁ and FVC, respectively. Of the 21 participants, 14 (66.7%) and 13 (61.9%) participants performed successful FEV₁ and FVC, respectively, on both devices. The proportion of acceptable tests was nominally higher using Pneumotrac (81%) device than using MIR (67%) spirometer, although there was no evidence of discordance between the acceptability of the 2 devices ($P=0.317$).

Among subjects with successful tests on both devices, Lin's concordance correlation demonstrated moderate agreement for spirometry outcomes (FEV₁ $r=0.955$, 95% confidence interval [CI]: 0.87–0.98; FVC $r=0.971$, CI: 0.91–0.99). The absolute mean difference in FEV₁ between Pneumotrac and MIR was 0.079 L. The 95% limits of agreement, defined as ± 2 SD of the paired differences, were -0.141 to 0.298 L. The absolute mean difference in FVC was 0.075 L, and the 95% limits of agreement were -0.171 to 0.322 L. These observed differences are relatively small and without evidence of systematic or volume-dependent bias (Fig. 1).

Discussion

Our current study aimed to determine the accuracy and feasibility for home-based research assessment of a handheld turbine spirometric device (MIR) and compared

TABLE 1. DEMOGRAPHICS AND BASELINE CLINICAL CHARACTERISTICS

Variable	Total (n=21)
Age, mean years (SD), range	8.7 (2.2), 6–12
Male, n (%)	11 (52.4)
Race, n (%)	
American Indian or Alaskan Native	1 (4.8)
Asian	1 (4.8)
Black or African American	5 (23.8)
White	13 (61.9)
Unknown	1 (4.8)
Ethnicity, n (%)	
Hispanic or Latino	5 (23.8)
Not Hispanic or Latino	15 (71.4)
Unknown	1 (4.8)
Gestational age (weeks), mean (SD)	25.8 (1.4)
Asthma, n (%)	9 (42.9)
Body mass index percentile, mean (SD)	36.6 (26.8)
Modified asthma control test, mean (SD)	24.2 (2.7)
% Predicted FEV ₁ , ^a mean (SD)	81.0 (18.1)
% Predicted FVC, ^a mean (SD)	90.4 (19.0)

^aPneumotrac measurements, based on Global Lung Function Initiative reference values.³

FEV₁, forced expiratory volume in one second; FVC, forced vital capacity; SD, standard deviation.

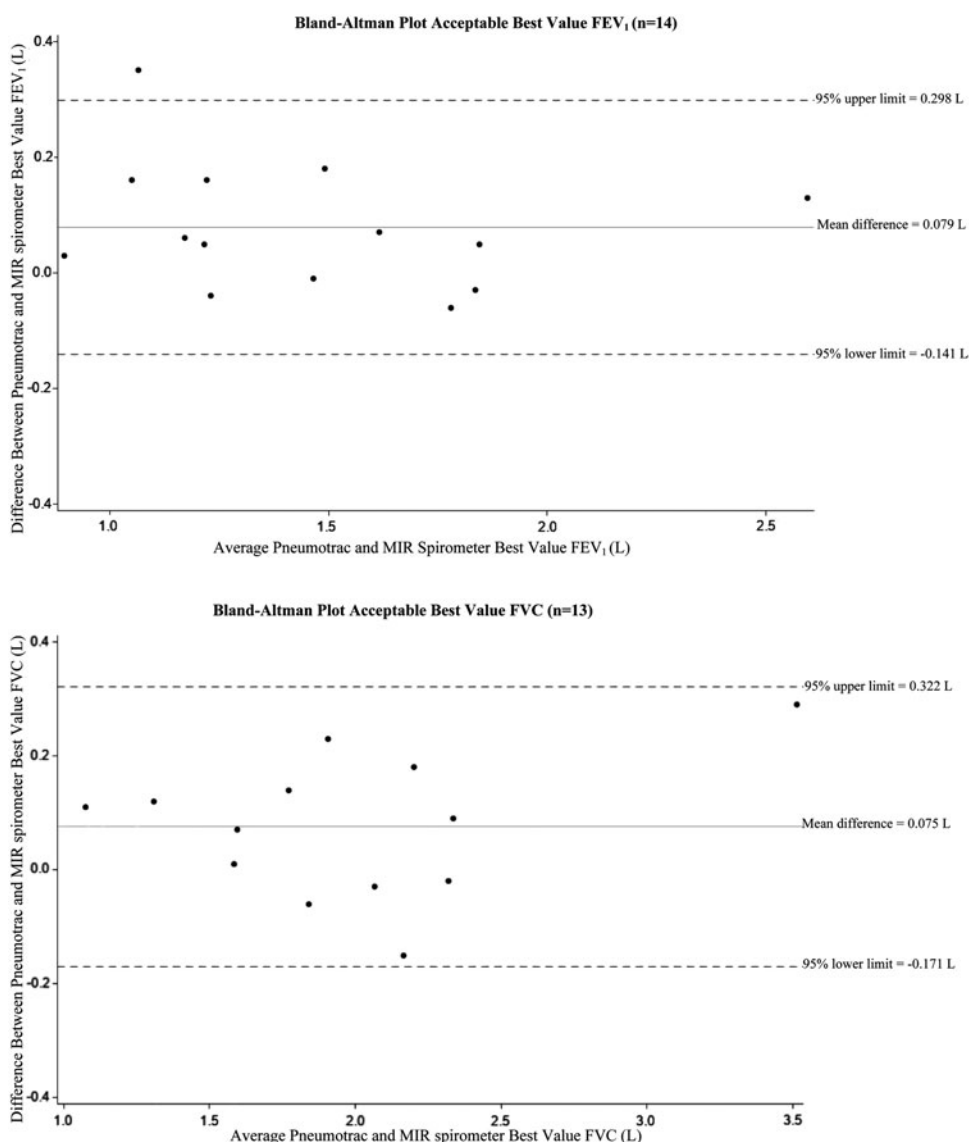


FIG. 1. Bland–Altman plots comparing acceptable Pneumotrac and MIR Spirometer measurements of absolute FEV₁ and FVC values in liters. FEV₁, forced expiratory volume in one second; FVC, forced vital capacity; MIR, Medical International Research.

pulmonary function indices measured with those from a conventional pneumotachograph spirometer (Pneumotrac) in school-aged children with a history of BPD. First, we determined whether the results were comparable as determined by acceptability between devices and found that although the Pneumotrac device had a nominally higher percentage of overall acceptable tests, this was not found to be significant. Airflow measurements obtained demonstrated a moderate concordance between the Pneumotrac and MIR devices.

In addition, the MIR device data approximate those obtained from the Pneumotrac device, where the mean difference of airflow measurements between both devices was relatively small for FEV₁ and FVC (79 and 75 mL, respectively), which is within the 2019 ATS/ERS guideline range for within-test repeatability of ≤ 150 mL. This suggests that the use of portable turbine spirometry gives accurate results for clinical research use. Despite the relatively small mean difference, it is important to note that the limits of agreement for FEV₁ and FVC are wide, therefore, should be interpreted with caution and not used interchangeably.

A larger sample size may be needed to fully capture the variability between devices. To our knowledge, this is the

first study to analyze the performance of a portable handheld spirometer in children with a diagnosis of BPD. There have been several studies comparing conventional and turbine handheld spirometry in the pediatric population with asthma and cystic fibrosis and have yielded comparable results with our current study.^{4–8} Published literature has shown good correlation and agreement between conventional and turbine spirometry; however, the limits of agreement were wide for FEV₁, and, therefore, the results were deemed not interchangeable,^{4–8} similar to the findings presented here.

According to Kruijzinga et al.,⁷ the reported wide limits of agreement are inherent to direct comparison of spirometers and higher in the pediatric population than in adults due their smaller lung volumes that may lead to bias. We believe this study is the first step to assess portable and easily accessible modes of pulmonary function testing for field-based research in children with BPD.

Limitations

Our study has some limitations. We acknowledge our small sample size; however, this was a convenience sample

due to the COVID-19 restrictions that were in place and limited to those with BPD. Device order randomization was not undertaken since the study's primary spirometry outcome is based on the Pneumotrac airflow measurements, and the addition of the MIR spirometer is merely an adaptation due to the COVID-19 pandemic. Repeated spirometry maneuvers can affect results either by altering airway resistance across multiple forced expiratory maneuvers or by fatigue, which may have influenced the lower acceptability and lower values of the MIR device. Future longitudinal studies with larger sample sizes and device randomization should be carried out to explore these findings further.

Conclusion

Within the confines of the relatively small sample, our data suggest utilizing turbine spirometers may be a useful and feasible way to perform pulmonary function testing for field research in children.

Author Disclosure Statement

No competing financial interests exist.

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