Utility of a Portable Hand-Held FEV1 meter for Monitoring Asthma in an Inner-City School Setting

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Monitoring forced expiratory volume in 1 second (FEV_1) is a valuable component to determine asthma control[1, 2] and indicate risk of future exacerbation[3] in children. However, use of spirometry by patients outside of healthcare facilities is limited by accessibility, staffing, time and cost.

The Electronic Peak Flow & FEV_1 Meter (PIKO-1, NSPIRE Health, Longmont, CO) is a handheld personal device for measuring FEV_1 values. It has the potential to offer personalized monitoring for children with asthma in non-clinical settings (home, school, or travel) and may be particularly beneficial to patients who have poor perception of their asthma symptoms.

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The few available published studies report conflicting results regarding the utility of PIKO devices[4–6], and are limited to either healthy volunteers or small numbers of asthmatics. Therefore, we aimed to determine the utility of PIKO in a large prospective cohort of children with asthma by determining its correlation and concordance of FEV_1 with traditional spirometry.

We performed serial side–by–side spirometry and PIKO-1 forced exhalation maneuvers in 242 school age children with asthma enrolled in the School Inner City Asthma Study[7]. Pneumotach spirometry (Koko spirometer, nSpire Health, Inc., Longmont, CO, USA), performed per American Thoracic Society guidelines[8], and PIKO-1 data were collected at a baseline (research facility) and follow-up visit (subject's elementary school) by trained research staff. Best efforts recorded at each visit were compared by Pearson correlation and intraclass correlation coefficient (ICC). However, two continuous measures can have similar distributions but render quite different actual values, leading to high *correlation* but poor *concordance* between the two measures. We used the Bland-Altman method to evaluate concordance of values between devices. The Bland-Altman method plots mean difference between each matched PIKO and spirometry measurement to identify systematic bias between devices measuring the same quantity (i.e. one consistently reads 20 units lower) or proportional bias (differences between devices do not agree equally through the range of measurements). Absolute liter flow was used for comparison rather than percent predicted to eliminate any discrepancies that might be imposed by prediction models.

In total, 441 paired FEV_1 measures, collected from 242 subjects, were analyzed. Subjects ranged in age from 4–12 (mean = 8) years and 50% female. The majority (n=166) of subjects self-identified as Black or Hispanic and 45% reported household income < $25,000/ year. On average, subjects had normal lung function at baseline (mean FEV_1 = 101% +/ −19%), and lacked airflow obstruction (Mean FEV_1/FVC =0.87 +/−0.08).

Spirometry FEV_1 and PIKO-1 FEV_1 were well correlated with Pearson coefficient = 0.80 (P<0.0001) (Figure) and ICC=0.75. Bland-Altman analysis demonstrated a mean difference between spirometry FEV_1 and PIKO-1 FEV_1 of 0.14L (95% limits of agreement = −0.40 to 0.68L) (Figure). Within session PFT variability was 0.4L for spirometry at 2 standard deviations, a much smaller range than seen in the PFT - PIKO confidence limits (1.1L), indicating that differences are due to distinctions in the devices themselves and not the within person techniques of using them. PIKO-1 FEV_1 was moderately biased to underestimate FEV_1 with increasing volumes, such that for every one liter increase in spirometry-FEV_1 the mean difference between spirometry and PIKO-1 increased by 0.19L (95% confidence interval = 0.12 to 0.25, p<0.001). There was no effect on the order of PFT or PIKO performance(p=0.88)

Overall, we found that PIKO-1 underestimated FEV_1 compared to pneumotach spirometry by an average of 0.14L, representing a 10% discrepancy from mean baseline FEV_1, but may have varied by more than 1L based on the limits of agreement. In context, 43% of values were greater than 150mL, the ATS/ERS standard for repeatability[8]. Additionally, we found that the difference in measures was not constant along the range of FEV_1 values. These

differences pose a substantial limitation to PIKO-1 use as a surrogate for measuring FEV_1 in clinical or research applications in asthmatic children.

Prior reports evaluating PIKO-1 device applications were conducted in either healthy volunteers[5, 6] or small number of asthmatics over short time periods[4]. To our knowledge, this is the first study to evaluate the validity PIKO-1 FEV_1 in a large number of asthmatic schoolchildren across formal (research clinic) and informal (school) settings.

Our findings are consistent with those presented by Rothe and colleagues[5] for healthy volunteers and Aguilar-Fernandez[9] in children with asthma in which good overall correlation was found with a consistent underestimation of FEV_1 by the PIKO device. While systematic bias was also present in those studies, the confidence of limitations was narrow suggesting that despite the numerical inaccuracy, once calibrated to the difference, the PIKO may offer reliable data. Within a pediatric cohort of asthmatics and healthy volunteers, Gochicoa-Rangel et al.[4] found the concordance between PIKO-1 and spirometry measurements to be lower in patients with partially controlled or uncontrolled asthma; precisely the population for whom the device would be most clinically useful. Similar to our findings, there was nearly a liter of variability in FEV_1 between devices.

We performed a comparative investigation of PIKO and spirometry in children with asthma recruited from the general community with minimal airflow obstruction. It is difficult to exclude the effect of within-subject variability when determining variability of the devices; however this was minimized by: 1) both maneuvers were overseen by trained research personnel, 2) produced at the same visit, and 3) only best efforts were analyzed after exclusion of poor quality spirometry. Additionally, by the nature of recruitment from a general, poor, urban population, with overall mild asthma it is likely that few subjects had spirometry experience prior to enrollment, unlike at least one study that found a more reliable relationship among pulmonary specialty clinic patients[9]. The technical performance may improve with practice.

In conclusion, the findings from this study suggest that the PIKO-1 device has limited utility in assessing FEV_1 in clinical or research settings in children with asthma. However, there may be applications for use of handheld devices longitudinally as a marker of clinical outcomes. Further investigation of its use in this respect and with different populations may prove the device more valuable.

Acknowledgments

Abbreviations

FEV$_1$	forced expiratory volume in 1 second
ICC	intraclass correlation coefficient

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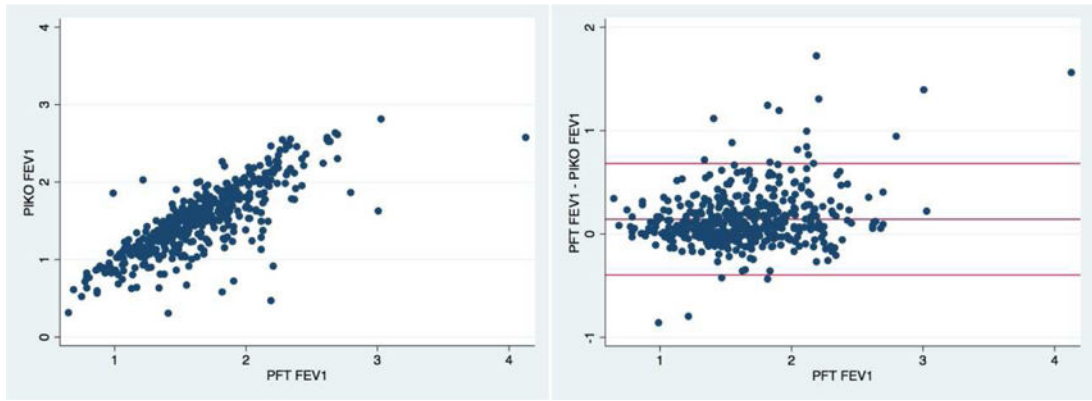
Figure. Relationship between PIKO-1 and Spirometry FEV$_1$

left panel: Scatterplot demonstrating correlation between PIKO-FEV$_1$ and PFT-FEV$_1$ (Pearson correlation = 0.8); right panel: Bland-Altman plot of PIKO and spirometry-derived FEV$_1$ (mean difference FEV$_1$ = 0.14L, 95% limits of agreement = −0.40 to 0.68L)