

European Respiratory Society Annual Congress 2012

Abstract Number: 1152

Publication Number: P722

Abstract Group: 1.6. General Practice and Primary Care

Keyword 1: Spirometry **Keyword 2:** COPD - diagnosis **Keyword 3:** Primary care

Title: Clinical assessment of a portable FEV₁/FEV₆ meter for the detection of airway obstruction

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Body: Objectives To evaluate the accuracy of the portable Vitalograph-COPD-6 device in the detection of airway obstruction. Methodology All participants underwent a measurement of FEV₁, FEV₆ and FEV₁/FEV₆ using the COPD-6 meter, and a conventional spirometry measuring FEV₁, FVC and FEV₁/FVC. Conventional spirometry was performed by highly trained lung function staff, whereas the COPD-6 meter was used by final-year medical students, according to the manufacturer's instructions. Subjects were randomized to determine which measurement was performed first. The FEV₁/FEV₆ ratio that corresponded to the optimal combination of sensitivity and specificity was determined from a ROC curve. Agreement was analyzed by calculating sensitivity, specificity, positive and negative predictive values (PPV and NPV), and the kappa-index. Results Test results of 147 subjects were analyzed. The prevalence of obstruction was 42%. The area under the ROC-curve was 0.946. The FEV₁/FEV₆ ratio that corresponded to the optimal combination of sensitivity and specificity was 73%. For this cutoff value sensitivity, specificity, PPV and NPV were 82%, 93%, 90% and 88%, respectively. The kappa-index was 0.76. Lowering the cutoff point to 70% resulted in sensitivity, specificity, PPV and NPV of 65%, 98%, 95% and 79%, respectively. For a FEV₁/FEV₆ cutoff point of 80%, they were 95%, 69%, 69% and 95%, respectively. Conclusions The portable Vitalograph-copd-6 device is an accurate device for detection of airway obstruction. Best sensitivity/specificity for FEV₁/FEV₆ was obtained with a fixed cutoff point of 73%. For screening purposes, high sensitivity (95%) can be reached when using an 80% threshold for FEV₁/FEV₆.