Comparison of a portable, pneumotach flow-sensor–based spirometer (Spirofy™) with the vitalograph alpha Touch™ spirometer in evaluating lung function in healthy individuals, asthmatics, and COPD patients—a randomized, crossover study

Deepak Talwar[1], S Balamurugan[2], Mahavir Modi[3], Sundeep Salvi[4], Meena Lopez[5*], Rushika Shah[5], Abhijit Vaidya[5], Monica Barne[6], Sapna Madas[7], Nandan Kulkarni[8], Sandesh Sawant[5] and Jaideep Gogtay[5]

Abstract

Background: Spirofy™ is India's first portable, pneumotach flow-sensor-based digital spirometer developed to diagnose asthma and chronic obstructive pulmonary disease (COPD). In this study, we compared the performance of the Spirofy™ device with that of the Vitalograph Alpha Touch™ spirometer in measuring the lung capacities of healthy individuals, asthmatics, and COPD patients. We also assessed the inter-device variability between two Spirofy™ devices.

Methods: In a randomized, three-way crossover, open-label study, we measured the differences in forced expiratory volume in the first second (FEV1) and forced vital capacity (FVC) between the Spirofy™ and Vitalograph Alpha Touch™ spirometers. A proportion of the FEV1/FVC ratio distribution of < 0.7 was used to compare the diagnostic accuracies of the Spirofy™ with Vitalograph™ Alpha Touch™ spirometers.

Results: Ninety subjects participated in this study. The mean ± SD FVC values obtained from the Spirofy™ 1, Spirofy™ 2, and Vitalograph Alpha Touch™ devices were 2.60 ± 1.05 L, 2.64 ± 1.04 L, and 2.67 ± 1.04 L, respectively. The mean ± SD FEV1 values obtained from the Spirofy™ 1, Spirofy™ 2, and Vitalograph Alpha Touch™ devices were 1.87 ± 0.92 (L), 1.88 ± 0.92 (L), and 1.93 ± 0.93 (L), respectively. A significant positive correlation was found between the FVC and FEV1 values recorded by Vitalograph Alpha Touch™, Spirofy™ 1, and Spirofy™ 2. As compared to Vitalograph Alpha Touch™, the Spirofy™ device showed good sensitivity (97%), specificity (90%), and overall accuracy (93.3%) at an FEV1/FVC ratio < 0.7. No inter-device variability was observed between the two Spirofy™ devices.

Conclusion: Spirofy™ is a portable and easy-to-use device and is as accurate as the standard Vitalograph Alpha Touch™ spirometer for the diagnosis of COPD and asthma