

European Respiratory Society Annual Congress 2013

Abstract Number: 1604

Publication Number: P4230

Abstract Group: 6.1. Epidemiology

Keyword 1: COPD - management **Keyword 2:** Physical activity **Keyword 3:** Epidemiology

Title: Patient reported outcomes for the measurement of physical activity in COPD patients. The PROactive tools

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Body: Introduction: The IMI-JU PROactive project has developed two patient reported outcomes (PRO) to measure physical activity in patients with COPD; a daily (evening) diary and a clinic visit PRO with a 7 day

recall. From an initial item pool developed from qualitative research with COPD patients, literature and expert input, this study reduced the set of items providing a measure of physical activity in COPD. Methods: 236 well-phenotyped COPD patients (68% male, mean age 67 y, mean FEV1 57%) with stable (n=221) and exacerbated (n=15) COPD used the draft PROs in a 6-week, open, randomised, 2-way cross-over, multi-centre study. Physical activity was also recorded with two activity monitors. An iterative process of item reduction included exploratory factor analysis, assessment of floor and ceiling effects, item-to-total and inter-item correlations, Rasch analysis, and differential item functioning. Results: Both PROs were structured in two domains: difficulty with physical activity and amount of physical activity. Item reduction was performed for each PRO and domain. For the difficulty domain, item reduction resulted in 5 items for the daily PRO and 10 items for the clinical visit PRO (from an initial 25 and 30 items, respectively). For the amount domain, item reduction resulted in 2 items and 2 outputs (steps and VMU) from activity monitors for both PROs. Confirmatory factor analysis supported the bidimensional structure of the resulting PROs. Conclusions: The PROactive daily and clinical visit PROs, combining a short list of items and two activity monitor variables, provide a valid measure of physical activity in COPD patients.