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Title: GOLD assessment of COPD patients: Impact of symptoms assessment choice

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Body: Background: The 2011 GOLD guidelines recommend combined COPD assessment using symptoms (modified Medical Research Council Dyspnoea [mMRC] ≥ 2 or COPD Assessment Test [CAT] ≥ 10) combined with a history of exacerbations in the past 12mo {0,1} vs 2+ and spirometric classification GOLD I/II vs III/IV. Four groups are identified, A: low symptoms+low risk; B: high symptoms+low risk; C: low symptoms+high risk; D: high symptoms+high risk. Objectives: Characterize the 4 groups using the ECLIPSE (Evaluation of COPD Longitudinally to Identify Predictive Surrogate Endpoints) cohort. Methods: 2028 COPD patients, FEV1<80%pred, provided baseline mMRC, SGRQ and previous 12mo history of exacerbations. SGRQ score ≥ 25 was used to replace the CAT ≥ 10 , using a validated conversion (Jones: BMCPulmMed 2011). Results: The 4 groups were comparable on age and gender, but had different characteristics. Size of patient groups classified by mMRC were A: 23%, B: 14%, C: 23%, D: 40%; by SGRQ, A: 9%, B: 28%, C: 3%, D: 60%. Compared to the SGRQ, patients classified as 'low symptoms' (GOLD A & C) using mMRC had worse health status, more fatigue and lower exercise capacity (6MWD). Categorising mMRC as 0 vs. ≥ 1 produced groups of similar size to those classified by SGRQ: A: 9%, B: 29%, C: 4%, and D: 59%. The kappa of agreement for group membership defined by SGRQ and mMRC increased from 0.2 (mMRC ≤ 1 vs ≥ 2) to 0.5 (mMRC 0 vs ≥ 1). Conclusions: The new assessment permits classification of COPD patients beyond airflow obstruction. GOLD recommends either CAT ≥ 10 or mMRC ≥ 2 as the symptomatic cut-point, but this analysis suggests that mMRC ≥ 1 will classify patients more closely to using the CAT. Clinicaltrials.gov NCT00292552; GSK study SCO104960.