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Title: Development and validation of an innovative self-administered computerized (SAC) version of baseline/transition dyspnea index (BDI/TDI) for evaluating breathlessness in patients with COPD: The BLAZE study

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Body: Introduction The Baseline (BDI) and Transition Dyspnea Index (TDI) are interview-based multidimensional instruments to assess breathlessness in patients with COPD. However, BDI/TDI interviewer process may introduce bias in the interpretation, leading to more variability in results. Innovative SAC versions of the BDI/TDI were developed and validated for the BLAZE study which allow patients to provide direct ratings of breathlessness based on activities of daily living. Methods A standardized methodology (MAPI guidelines) was followed to translate the SAC BDI/TDI and 45 COPD patients participated in tests for its acceptability. In-depth interviews to evaluate comprehension and acceptability using laptop computers were conducted in Dutch, Danish, English, Flemish, French, German, and Spanish (5 patients in each language). Results Most patients liked the SAC versions; only 4 patients had problems using computer mouse to click on the right answer for the BDI. The items were understood with no difficulties; most challenging issue was the comprehension of the equivalents of "Baseline" and "Transition". 42% of the patients had difficulties with the instructions to select answers on the TDI. These difficulties were resolved after patients answered the practice question designed to help the patients become familiar with clicking in a box for BDI and using the up-and-down arrows for TDI. Conclusion The SAC BDI/TDI has the potential to advance our knowledge of patient-reported outcomes and be a beneficial tool for assessing breathlessness related to activities of daily living in COPD patients.