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Feasibility of Utilizing One-Day vs Seven-Day Results of the Pulmonary Arterial Hypertension (PAH)-SYMPACT Tool

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Background: Patient-reported outcomes (PRO) are important in clinical research and treatment of patients with PAH but are not widely utilized in clinical practice. PAH-SYMPACT is the only PAH-specific instrument developed and validated in accordance with FDA guidance on PRO development and is thus appropriate for clinical practice and clinical studies. While a weekly recall of the impact of PAH on daily living is captured on one day, symptoms are measured using the average symptom score of consecutive 7-day daily item scores. Daily reporting may make PAH-SYMPACT impractical outside of clinical trial settings because it may overburden patients. We evaluated a revised version of PAH-SYMPACT in which patients report their symptoms on one day instead of daily for 7 days.

Methods: Data from the SYMPHONY study (NCT01841762) were analyzed. The average symptom scores in each domain (cardiopulmonary symptoms and cardiovascular symptoms) obtained with daily reporting for one week were compared to those reported on day 7 using Spearman's rank correlation and weighted kappa methods.

Results: Spearman's correlation coefficients comparing the weekly average and day 7 scores were very high (≥ 0.92) for cardiopulmonary symptoms and high (≥ 0.87) for cardiovascular symptoms. Similar results were found with the weighted kappa method. Spearman's correlation coefficients between daily symptoms and the weekly average were generally high regardless of the day, but correlations were stronger as the week progressed (day 1 through day 6) and were generally highest on day 6 (0.73 to 0.92). Day 7 symptom scores differentiated well between FC I/II and FC III/IV PAH and were sensitive to change in symptoms as measured by the Patient Global Assessment of Disease Severity.

Conclusions: These data suggest that the one-day PAH-SYMPACT is feasible. This one-day tool is well-suited for incorporation into clinical practice and thus may facilitate more widespread use.



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