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Title: COPD-associated severe pulmonary hypertension (COPDPH): Results of a 16-weeks prospective multicenter, double-blind, placebo-controlled randomized clinical trial (RCT) [SPHERIC-1 (http://clinicaltrials.gov/ct2/show/NCT01441934)] investigating the effect of sildenafil citrate (Sld) on pulmonary vascular resistance (PVR) and PaO2

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Body: SPHERIC-1 is a pilot RCT aimed to investigate the hemodynamic effect and safety of sustained Sld administration in COPDPH. Treatment: Sld 20 mg TID vs placebo (ratio 2:1) for 16 weeks. Inclusion criteria: stable COPD, rest PaO2 ≥60 mmHg (±supplemental O2) and PaCO2 ≤55 mmHg, PAPm ≥35 mmHg (if FEV1 <30%) or PAPm ≥30 mmHg (if FEV1 ≥30%). Sld-induced hypoxemia was ruled out by a post-first-dose PaO2 assessment. Endpoints: reduction of PVR and safety (drop of PaO2). Results: 31 pts were randomized in 7 centers. Demographic, hemodynamic and respiratory parameters at baseline were comparable in the 2 groups. Among 25 patients who completed the study (15 on Sld) PVR decreased significantly in the treated group (9.66±3.3 Wood units to 8.01±2.6 vs 9.21±3.3 to 9.34±3.6, p<0.05), (Figure 1) and cardiac index (CI) has risen (2.27±0.3 L/min/m² to 2.50±0.4 vs 2.52±0.7 to 2.29±0.4, p<0.01). BODE Index score decreased in Sld group (5.2±2.5 to 4.8±2.6 vs 4.67±2 to 5.22±1.7, p<0.05). Sld was safe (no SAE) and PaO2 didn't worse at the end of study (73.3±11.8 to 69.0±7.8 mmHg, p=0.49). Conclusions: Sld 20 mg TID for 16 weeks safely improved PVR, CI and BODE score in selected pts with COPD-associated severe PH.