Abstract: 4282

Pulmonary artery denervation in patients with residual pulmonary hypertension after pulmonary endarterectomy: one-year results of the first-in-man, sham-controlled, pilot randomized clinical trial

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Topic(s):
Pulmonary Hypertension

Citation:

Funding Acknowledgements:
Grant from Biosense Webster

Background: Pulmonary endarterectomy (PE) is the method of choice in patients with chronic thromboembolic pulmonary hypertension (CTEPH). Despite the positive effect after surgery combined with medical treatment, 10-40% of patients develop residual CTEPH. Pulmonary artery denervation (PAD) is a novel treatment in PAH with optimistic results but was not tested in patients with residual CTEPH.

Objective: To assess the safety and efficacy of PAD using remote magnetic navigation system in patients with residual CTEPH after PE.

Methods: 278 patients with CTEPH after PE were screened. 50 patients (mean age 47.6±14.3, 50% female) with a history of residual CTEPH (a resting pulmonary artery pressure =25 mm Hg or pulmonary vascular resistance > 400 dyn x sec x cm-5 despite medical therapy 6 months after PE) were randomized into two groups: PAD (n=25; PAD group) or medical therapy with riociguat (n=25; MED group). In both groups right heart catheterization (RHC) was performed after randomization. In the PAD group, remote magnetic navigation system was used to target sympathetic nerve fibers, located near bifurcation and ostia of the main branches of right and left pulmonary arteries. This study was conducted as double-blind and sham-controlled and the primary endpoint was change in pulmonary vascular resistance (PVR) by RHC at 12 months. Secondary endpoints included 6-minute walk test (6MWT), pulmonary artery pressure, and clinical outcomes. All patients were followed for 12 months after randomization. Unpaired t-test and Fisher’s exact test were used for between-group comparisons of continuous and categorical variables, respectively. A p value of less than 0.05 was considered statistically significant.

Results: Two patients (one in each group) developed groin hematoma which resolved without any consequences. At the end of 12 months, the PVR was significantly low in PAD group as compared with MED group (343±149 dyn x sec x cm-5 vs 444±145 dyn x sec x cm-5, respectively; mean difference -101, 95% confidence interval: -193 to -10; p=0.032). The mean, systolic and diastolic PA pressure was also reduced significantly in PAD group compared to MED group (25.8±7.3 mm Hg vs 33.8±6.4 mm Hg, 46.2±14.1 mm Hg vs 54.2±8.1 mm Hg, 13.2±5.3 mm Hg vs 20.2±4.8 mm Hg; p <0.001, p=0.002, p<0.001, respectively). The PAD group demonstrated significant improvement of the 6MWT over MED group (470±84 m vs 399±116 m, respectively, p=0.031). In the PADN group (4%) patient was hospitalized due to heart failure progression compared to 7 (29%) patients in MED group (p=0.049). One patient in PAD group and two patients in MED group died.

Conclusions: Pulmonary artery denervation in patients with residual pulmonary hypertension was safe and
effective, and resulted in substantial reduction of pulmonary vascular resistance and pulmonary artery pressure during 12 months follow up, accompanied by improved 6-minute walk test and reduced need for hospitalization. Clinical Trials Registration: NCT02745106