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Radiofrequent pulmonary artery denervation - alternative treatment of residual chronic thromboembolic pulmonary hypertension. Results of a randomized pilot study

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Background/introduction. Pulmonary endarterectomy (PEA) is the gold standard of CTEPH treatment. However, residual CTEPH develops in 10-40% of patients after PEA, which leads to progression of right ventricular insufficiency. Currently, the only way to treat residual CTEPH is PAH-specific drug therapy. However, this treatment is not indicated for all patients because of the arterial hypotension and dyspeptic disorders.

Purpose. To assess the safety and efficacy of radiofrequent pulmonary artery denervation (PADN) in patients with residual CTEPH after PEA.

Methods. In 2015, a randomized pilot study was conducted to evaluate PADN in patients with residual CTEPH (NCT 02745106). 278 patients with CTEPH after PEA were screened. In 62 of them, according to the echocardiography, residual CTEPH (systolic pulmonary artery pressure (PAP) ≥45 mm Hg) was detected. In 50 patients, residual CTEPH was confirmed during right heart catheterization (RHC): mean PAP = 25 mmHg and pulmonary vascular resistance (PVR) > 400 dyn×s×cm-5. Patients were randomized into two groups: 25 in PADN group and 25 in drug therapy group with riociguat. Mean age was 39 years [26; 51]. The mean duration after PEA was 4.5 years [1; 8.5]. The primary end point was PVR in the short-term and long-term follow-up. Secondary end points were: mean PAP, cardiac output, 6-minute walk test (6MWD) and NYHA functional class. All patients were followed up for 12 months after discharge. The PADN procedure was performed using electrophysiological catheter Navistar RMT Thermocool, Biosense Webster, Diamond Bar, CA, USA and non-fluroscopic 3D navigation system.

Results. There was no mortality. In two patients (one in each group) hematoma developed in femoral vein puncture site without any consequences. The mean surgery time was 105 [93; 120] minutes. After 12 months, PVR was significantly lower in the PADN group compared with the drug treatment group (343 ± 149 dyn×s×cm-5 vs 444 ± 145 dyn×s×cm-5, respectively; mean difference - 101, 95% confidence interval from -193 to -10; p = 0.032). The mean PAP was also significantly lower in the PADN group (25.8 ± 7.3 mm Hg vs. 33.8 ± 6.4 mm Hg, p <0.001). We noticed a significant improvement of 6MWD test in PADN group compared with the drug treatment group (470 ± 84 m versus 399 ± 116 m, respectively, p = 0.031). In PADN group 1(4%) patient was hospitalized due to progression of heart failure compared with 7 patients (29%) in the drug treatment group (p = 0.049). One patient (4%) in the PADN group and two patients (8%) in the drug treatment group died due to progression of heart failure over the long-term follow-up.

Conclusions. The PADN technique showed its safety and efficacy in the treatment of patients with residual CTEPH and can be used in clinical practice. The obtained first results showed that the proposed PADN, together with optimal medical therapy, can take a place in the treatment of residual CTEPH after PEA.