Safety and efficacy of cryoballoon-ablation for atrial fibrillation performed at local hospitals: results of the german register on cryoballoon-ablation in local hospitals (RE-GIONAL)

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Background: Pulmonary vein isolation (PVI) using cryoballoon ablation (CBA) has become an established procedure for the treatment of symptomatic paroxysmal and persistent atrial fibrillation (AF). The safety and efficacy of PVI at community hospitals with low to moderate case numbers is unknown.

Aim: To determine safety and efficacy of PVI using CBA performed at community hospitals with limited annual case numbers.

Methods: 1004 PVI performed consecutively between 01/2019 and 09/2020 at 20 community hospitals (each <100 PVI using CBA/year) for symptomatic paroxysmal AF (n = 563) or persistentAF (n= 441) were included in this registry. CBA was performed considering local standards. Procedural data, efficacy and complications were determined.

Results: Mean number of PVI using CBA/year was 59 ± 26 . Mean procedure time was 90.1 ± 31.6 min and mean fluoroscopy time was 19.2 ± 11.4 min. Isolation of all pulmonary veins could be achieved in 97.9% of patients, early termination of CBA due to phrenic nerve palsy was the most frequent reason for incomplete isolation. There was no in-hospital death. 2 patients (0.2%) suffered a clinical stroke. Pericardial effusion occurred in 6 patients (0.6%), 2 of them (0.2%) required pericardial drainage. Vascular complications occurred in 24 patients (2.4%), in 2 of these patients (0.2%) vascular surgery was required. In 48 patients (4.8 %) phrenic nerve palsy was noticed which persisted up to hospital discharge in 6 patients (0.6%).

Conclusions: PVI for paroxysmal or persistent AF using CBA can be performed at community hospitals with high efficacy and low complication rates despite low to moderate annual procedure numbers.