

## **MEDAFI- Trial (microembolization during ablation of atrial fibrillation):comparison of pulmonary vein isolation using cryo balloon technique versus radiofrequency energy**

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**Purpose:** Thromboembolic cerebral events (TCE) after pulmonary vein isolation (PVI) typically occur within 24 hours of the ablation procedure with a high risk period extending for the first two weeks following ablation. A number of potential explanations for this complication have been proposed. These include thrombi on stationary sheaths, char formation at the tip of ablation catheter, and disruption of a thrombus originated from extended destruction of endothelium surface. The aim of our prospective study was to test the hypothesis if the recently developed cryo balloon technique (CRYO) is associated with lower risk of TCE than conventional radiofrequency ablation (RF) technique.

**Methods:** PVI was performed in 89 pts (paroxysmal AF N=67), either with CRYO (N=45) or RF (N=44). In all patients at least PVI of all targeted pulmonary veins was the therapeutic aim. Three days before intervention, Phenprocoumon was stopped and replaced by subcutaneous low molecular weight heparin. During the catheter procedure, an infusion of heparin was maintained to achieve an activated clotting time > 300 seconds. Oral anticoagulation with Phenprocoumon was started on day after PVI, targeting an international normalized ratio of 2.0 to 3.0 for at least 3 months. The MRI examinations were performed on a 1.5 Tesla scanner one day before, one day after, 3 and 6 months after PVI: T1- and T2- weighted TSE-sequences (TR/TE = 500/14ms, TR/TE = 2760/81ms). Liquor suppressed TIRM-sequence (TI/TR/TE=2500/8000/104ms). Diffusion weighted EPI- sequence (TR/TR=2500/84ms, 1000ms pre pulse delay). Old vascular lesions as well as fresh lesions were differentiated.

**Results:** Totally in 11 out of 89 (12.3%) patients we observed chronic lesions before PVI (Cryo n=4, RF n=7). The number of old lesions didn't change after 3 and 6 months. Seven patients (7.8%) developed acute lesions one day after PVI (CRYO n=4, RF n=3) and no further acute lesions after 3 and 6 months. There were no significant differences between the number of acute cerebral lesions using CRYO or RF. No symptomatic TCE were observed in our study, even in the patients with cerebral acute lesions.

**Conclusion:** A considerable portion of patients with AF and no neurological symptoms have chronic cerebral lesions supposed possibly due to AF. Additional acute lesions could be added after PVI. The detected equivalent rate of cerebral lesions independently of the used energy source, underline the hypothesis that thrombus originated from extended destruction of endothelium surface is not the only cause of cerebral lesions.