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Time-to-isolation-guided cryoballoon pulmonary vein isolation reduces esophageal and mediastinal alterations detected by endoscopic ultrasound

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Background: Pulmonary vein isolation (PVI) is recommended for treatment of symptomatic atrial fibrillation. Cryoballoon ablation is an emerging safe and efficient technique for achieving PVI. Nevertheless, structural alterations of the mediastinum and/or the oesophagus, which seem to be associated with an increased risk of the lethal complication of an atrio-oesophageal fistula, have been described.

Purpose: MADE-PVI (Mediastino-oesophageal Alterations Detected by Endosonography after PVI) aimed at evaluating safety of cryoballoon PVI in relation to two different freeze protocols. As a time-to-isolation (TTI)-guided protocol has been reported to be as effective as a conventional "two freeze protocol", we hypothesized that a TTI-guided protocol causes less peri-atrial and -oesophageal lesions.

Methods: 70 consecutive patients were scheduled for de novo cryoballoon (2nd generation) PVI employing either a conventional freeze protocol (Group A: n=35: 2x180s per vein) or a TTI-guided approach (Group B: n=35; freeze time: TTI+120s per vein or 1x180s in case TTI could not be measured). Structural oesophageal and mediastinal alterations (e.g. ulceration, oedema) were assessed by endoscopy and endosonography blinded prior and post ablation.

Results: Irrespective of used freeze protocol, ablation significantly increased atrio-oesophageal distances, including distance to left and right inferior pulmonary vein ostia as well as to the posterior wall of the left atrium (all $p < 0.001$). In general, postinterventional mediastinal oedematous alterations were detected in 47 patients (70%) with a mean size of 14mm (± 0.9 mm), while only 10 patients (15%) revealed a large mediastinal oedema > 20 mm. Oesophageal thermal lesions occurred in 3 patients (4%) including 1 deep ulceration, which coincided with a large mediastinal oedema. The two freeze protocols had a distinct impact on mediastinal lesions as mean size of oedematous alterations and occurrence of large mediastinal oedema were significantly increased in Group A vs. Group B (17 mm vs. 11 mm, $p < 0.001$; 26% vs. 6%, $p = 0.029$). Furthermore, every oesophageal lesion was detected in patients in group A. Nonetheless, no major complication occurred in either group.

Conclusions: The present prospective study clearly demonstrates a significant impact of freeze protocol on post-interventional mediastino-oesophageal alterations. A TTI-guided protocol employing 2nd generation cryoballoon reduces mediastino-oesophageal lesions and may reduce complications.