

First insight into a novel irrigated radiofrequency ablation balloon

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Background: A novel irrigated RF balloon (RFB) for pulmonary vein isolation (PVI) was recently released in selected centers. It is a 28 mm open irrigated balloon with 10 unipolar electrodes on its surface to deploy a circular ostial lesion set around the PVs. An inner lumen spiral catheter allows for real time PVI visualization during the ablation.

Methods: Data from consecutive RFB procedures were collected and analysed. After a single transeptal puncture and selective PV angiograms a 3D map of the left atrium was acquired. Sequential PVI was performed using the RFB: each application lasted 60 seconds, the posterior electrodes were identified to stop the energy delivery after 20 seconds. Real time to isolation data were acquired. A 3D bipolar remap was finally performed to observe the level of isolation. A temperature probe was used to monitor the local esophageal temperature (LET) with a cut off of 39°C. Acute procedural data and complication were collected. Endoscopy was scheduled the day after procedure.

Results: Data from 10 consecutive RFB procedures were analyzed: 6/10 patients were male, 67 ± 9 years old, 8/10 with history of paroxysmal AF. A total of 36 PVs were targeted and isolated with the RFB, with a mean of 7,3 ± 4,0 applications per patient and 2,0 ± 1,2 applications per PV. First pass "single shot" isolation was achieved in 22/36 (61%), time to isolation during the first application was observed in 29/36 (80%) PVs, but an acute reconnection was observed in 10/29 (35%) isolated PVs. Mean time to sustained isolation was 13 ± 5 sec., mean time to non-sustained isolation was significantly longer (29 ± 17 sec; p = 0,001). Procedure time was 57 ± 16 min., left atrial dwell time 50 ± 14 min, ablation phase time 29 ± 14 min and fluoroscopy time was 10 ± 4 minutes. An esophageal temperature above 39°C was recorded in 2/36 PVs. No phrenic nerve palsy was recorded. 7/10 patients underwent endoscopy and no thermal lesions were detected. No other complications were recorded.

Conclusion: The novel irrigated RFB seems to allow an effective, safe and fast pulmonary vein isolation. More studies are needed to optimize energy dosing to possibly increase the rate of durable single shot PVI.