Catheter maneuverability in isolating the right inferior pulmonary vein with a new multielectrode RF balloon catheter in Paroxysmal Atrial Fibrillation patients from a multi-center evaluation

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Introduction: Anatomical features of the right inferior pulmonary vein (RIPV) can make electrical pulmonary vein isolation (PVI) challenging with single shot technologies. The multielectrode RF balloon (RFB) catheter is a compliant balloon which offers the capability to deliver RF through any or all of 10 RF electrodes. We hypothesized that the compliant nature of the RFB, as well as the ability to directionally tailor and dose RF delivery will allow efficacious PVI of the RIPV on par with other targeted PVs. The purpose of this study is to evaluate maneuverability of the RFB catheter in achieving RIPV isolation in terms of procedural efficiency and acute success, and to compare that with the overall PV isolation procedure.

Methods: Eighty-five evaluable (85) patients with paroxysmal AF underwent PVI using the RFB at 6 European centers as part of the prospective multi-center SHINE study. Power of 15 watts unipolar RF energy was delivered for 20 seconds for the posterior facing electrodes and for 60 seconds for the others. A spiral diagnostic catheter was placed just distal to the RFB to allow assessment of PVI in real time. RIPV catheter maneuverability time was derived from RF generator data, calculating the time from the last RF termination of the preceding vein to the first RF ablation on the RIPV. Time to effect (TTE) was recorded from the first RF application to achieving single-shot isolation of a targeted PV. If multiple attempts were needed for isolation of a targeted PV, no TTE was estimated. Single-shot success rate was defined as percentage of targeted PVs being isolated by one valid ablation application without further touch-up. PVI rate was defined as percentage of targeted PVs being isolated before adenosine challenge, regardless the number of ablation application. Acute reconnection rate was defined as percentage of targeted PVs showing post-ablation reconnection after adenosine challenge. Acute effectiveness rate was defined as percentage of subjects with entrance block confirmation at the end of the case.

Result: Interpretable electrical signals on the diagnostic catheter were seen in 327 PVs in 83 patients. Table 1 summarizes the performance of the RFB catheter in the ablation of RIPV and overall targeted PV. For all variables, the performance of RFB for isolating RIPV was comparable to the that for other PVs. There were no cases of phrenic nerve palsy reported as primary adverse event.

Conclusion: In a multicenter evaluation, the RFB demonstrated easy catheter maneuverability with very high procedural efficiency and acute success for isolating the RIPV that was comparable to all
targeted PVs.