Learning Curve for Pulmonary Vein Isolation with a Multi-Electrode Radiofrequency Balloon Catheter in Six European Centers from the SHINE Study

Richard Schilling  
Claudio Tondo  
Stefania Riva  
Massimo Grimaldi  
Dhiraj Gupta  
Gian-Battista Chierchia  
Baohui Zhang  
Vivek Reddy

Introduction : Pulmonary Vein Isolation (PVI) is considered the cornerstone of atrial fibrillation ablation. A new multi-electrode radiofrequency balloon catheter (RFB) introduced a single-shot approach to PVI with its 10 irrigated, flexible gold surface electrodes to directionally-tailor energy delivery. The concurrent use of a 10-pole circular diagnostic catheter provides operators with real-time PV electrograms to verify entrance block. These features should lead to simpler and faster PVI. Here we present the effect of operator experience and associated learning curve on the AF ablation procedure efficiency in paroxysmal AF patients from the SHINE multicenter study.

Methods : Seven operators performed PVI in 93 patients (age 60.2±9.8 yrs, 64.5% male) at 6 centers using the RFB. The first 8 subjects were roll-in cases, and 85 subjects comprised of the evaluable cases. For each center, procedural data from the first (roll-in) case to the last evaluable case were plotted against the number of ablations. Generalized linear mixed models and/or spline were fitted to examine the trend in procedure efficiency over number of ablation procedures performed. The operating physicians were treated as random effect in the models. Procedural data included in the analyses (and its definition) were the following: total procedure time (time from first femoral puncture to catheter removal, test with isoproterenol or adenosine, and the waiting time after ablation), total fluoroscopy time, and balloon dwell time (time from first RFB insertion until RFB removal). The procedural data for roll-in and evaluable cases were also summarized using mean and standard deviation.

Result : Total procedure time significantly decreased by an average of 75.3 minutes after the first procedure was completed (Figure). Similarly, total fluoroscopy duration and balloon dwell times decreased by an average of 10.4 minutes and 32.9 minutes, respectively, after the first procedure. Procedural efficiencies improved from roll-in cases compared to subsequent evaluable cases (total procedure time: 158.4±59.05 vs. 87.6±22.25 minutes, total fluoroscopy time: 23.6±19.47 vs. 10.9±9.12 minutes, and balloon dwell time: 76.6±36.39 vs. 40.3±16.69 minutes).

Conclusion : Procedural efficiency outcomes across all operators improved after just one PVI procedure, demonstrating that the new RFB can be adopted by new operators with a short learning curve.