Radiofrequency Hot Balloon Catheter Ablation of Atrial Fibrillation: Results of a Multicenter Clinical Trial in Japan

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Background: We evaluate the safety and efficacy of a radiofrequency hot balloon catheter (Toray-Satake Balloon; TSB) for the treatment of the patients with AF. Methods and Results: A total of thirty patients (26 men, 60±9 years) with drug-resistant AF (paroxysmal n=26, persistent n=4) were enrolled in this study. Under general anesthesia (n=12) or deep sedation (n=18), we performed isolation of all PVs including PV antrum, only by use of TSB. The center temperature of the balloon (60-70°C) and the delivery time of RF energy (90-240 seconds) were determined by the wall thickness of each PV, measured by intra-cardiac echo. Complete PV isolation was observed in 110 of 121 PVs (91%), and decreased PV potentials were left in 4/31 (13%) at right superior PV, 4/30 (13%) at left superior PV, and 3/30 (10%) at left inferior PV. Total procedure times were (102±27min). Total fluoroscopic times and total application times were (31±14min) and (12±2 times), respectively. After a single procedure, twenty-seven of 30 patients (87 %) were free from AF without anti-arrhythmic drugs during 6 months follow-up period. There were no complications such as stroke, esophageal fistula, symptomatic PV stenosis, phrenic nerve palsy, pyloric spasm. Conclusion: Ablation by TSB might be time-saving, safety and quite promising therapy for the patients with AF. Keywords: atrial fibrillation, ablation