Infective endocarditis after transcatheter pulmonary valve replacement using the Melody valve: combined results of 3 prospective North American and European studies.

Abstract:
Transcatheter (percutaneous) pulmonary valve (TPV) replacement has emerged as a viable therapy for right ventricular outflow tract conduit dysfunction. Little is known about the incidence, clinical course, and outcome of infective endocarditis (IE) after TPV implant. We reviewed combined data from 3 ongoing prospective multicenter trials to evaluate the experience with IE among patients undergoing TPV replacement using the Melody valve. Any clinical episode reported by investigators as IE with documented positive blood cultures and fever, regardless of TPV involvement, was considered IE. Cases were classified as TPV-related if there was evidence of vegetations on or new dysfunction of the TPV. The 3 trials included 311 patients followed for 687.1 patient-years (median, 2.5 years). Sixteen patients were diagnosed with IE 50 days to 4.7 years after TPV implant (median, 1.3 years), including 6 who met criteria for TPV-related IE: 3 with vegetations, 2 with TPV dysfunction, and 1 with both. The annualized rate of a first episode of IE was 2.4% per patient-year and of TPV-related IE was 0.88% per patient-year. Freedom from TPV-related IE was 97±1% 4 years after implant. All patients were treated with intravenous antibiotics, 4 had the
valve explanted, and 2 received a second TPV. There was 1 sepsis-related death, 1 patient died of sudden hemoptysis, and 2 patients developed recurrent IE. Bacterial endocarditis has occurred in all 3 prospective multicenter studies of the Melody valve in North America and Europe. Most cases did not involve the TPV and responded to antibiotics. More data are necessary to understand risk factors in this population.