Eur J Cardiothorac Surg 2016;50(6):1139-1148.

Early and mid-term outcomes of 1904 patients undergoing transcatheter balloon-expandable valve implantation in Italy: results from the Italian Transcatheter Balloon-Expandable Valve Implantation Registry (ITER).

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Abstract

OBJECTIVES: The aim of this multicentre study is to report the clinical experiences of all patients undergoing transcatheter aortic valve implantation (TAVI) with a balloon-expandable device in Italy.

METHODS: The Italian Transcatheter balloon-Expandable valve Registry (ITER) is a real-world registry that includes patients who have undergone TAVI with the Sapien (Edwards Lifesciences, Irvine, CA, USA) bioprosthesis in Italy since it became available in clinical practice. From 2007 to 2012, 1904 patients were enrolled to undergo TAVI in 33 Italian centres. Outcomes were classified according to the updated Valve Academic Research Consortium (VARC-2) definitions. A multivariable analysis was performed to identify independent predictors of all-cause mortality.

RESULTS: Mean age was 81.7 (SD:6.2) years, and 1147 (60.2%) patients were female. Mean Logistic EuroSCORE was 21.1% (SD:13.7). Transfemoral, transapical, transaortic and transaxillary TAVI was performed in 1252 (65.8%), 630 (33.1%), 18 (0.9%) and 4 (0.2%) patients, respectively. Operative mortality was 7.2% (137 patients). The VARC-2 outcomes were as follows: device success, 88.1%; disabling stroke, 1.0%; life-threatening and major bleeding 9.8 and 10.5%, respectively; major vascular complication, 9.7%; acute kidney injury, 8.2%; acute myocardial infarction ≤72 h, 1.5%. Perioperative pacemaker implantation was necessary in 116 (6.1%) patients. At discharge, the mean transprosthetic gradient was 10.7 (SD:4.5) mmHg. Incidence of postoperative mild, moderate or severe paravalvular leak was, respectively, 32.1, 5.0 and 0.4%. A total of 444/1767 (25.1%) deaths after hospital discharge were reported: of these, 168 (37.8%) were classified as cardiac death. Preoperative independent predictors of all-cause mortality were male gender (HR: 1.395; 95% CI:1.052-1.849); overweight, BMI 25-30 kg/m2 (HR: 0.775; 95% CI: 0.616-0.974); serum creatinine level (every 1 mg/dl increase; HR: 1.314; 95% CI:1.167-1.480); haemoglobin level (every 1 g/dl increase; HR: 0.905; 95% CI:0.833-0.984); critical preoperative state (HR: 2.282; 95% CI: 1.384-3.761); neurological dysfunction (HR: 1.552; 95% CI:1.060-2.272); atrial fibrillation (HR: 1.556; 95% CI:1.213-1.995); pacemaker rhythm (HR: 1.948; 95% CI:1.310-2.896); NYHA Class III or IV (HR: 1.800; 95% CI:1.205-2.689 or HR: 2.331; 95% CI:1.392-3.903, respectively).

CONCLUSIONS: TAVI with a balloon-expandable device in the 'real world' shows good mid-term outcomes in terms of survival, technical success, valve-related adverse events and haemodynamic performance.