

Trends in population characteristics, 30-day outcomes and one-year survival in patients treated with TAVI

Since the first-in-man transcatheter aortic valve implantation (TAVI) performed in our center in 2002, this technique has been increasingly accepted by the medical community as a viable and established option in patients with severe aortic stenosis (AS) either inoperable or at high risk for surgical valve replacement. With the growing experiments of the community and improvement in devices and catheters, indications of TAVI might become even wider. In this study, we aimed to evaluate the trends in feasibility and safety of transfemoral transcatheter aortic valve implantation (TAVI) from 2010 to 2013 in our pioneered center.

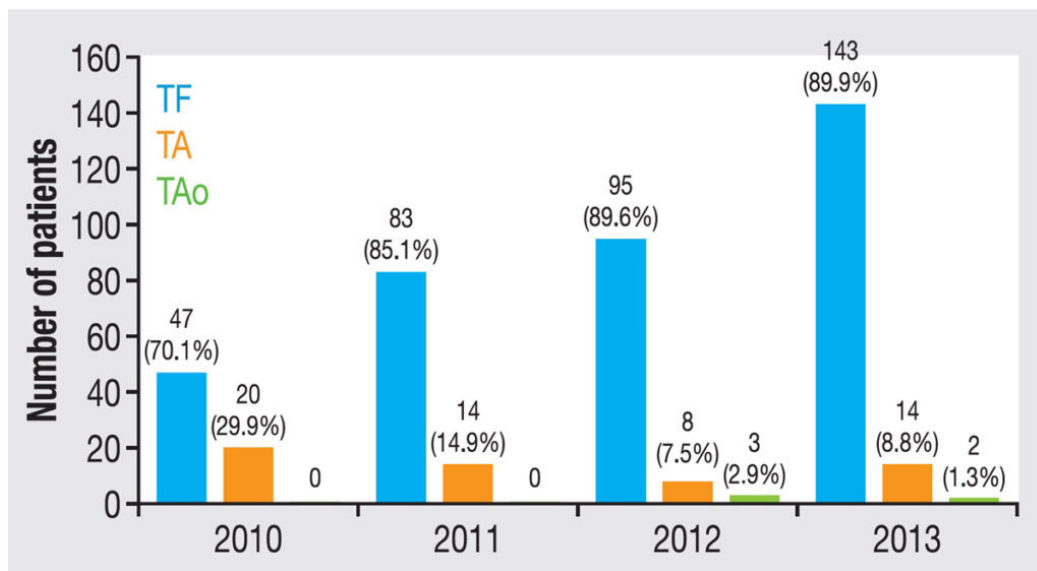


Fig. 1. Bar graph representation of the annual number (and percentage) of procedures over the period of 4 years via trans-femoral (TF, blue), transapical (TA, red) and transaortic (TAo, green) approaches.

Between January 2010 and December 2013, all consecutive patients undergoing TAVI in the Department of Cardiology of Rouen Hospital were included in a prospective registry. Transfemoral procedures were performed in a conventional cardiac catheterization laboratory, with sterile precautions using local anaesthesia and conscious sedation (nalbuphine 5 mg and midazolam 1 mg) in all cases. TTE was not used during the procedure and the percutaneous approach was performed using a preclosing system (Prostar; AbbottInc., Chicago, IL, USA). All of the equipment was present and ready to use in the catheterization laboratory, and the anaesthesiologist, echocardiographer and surgeon were immediately available in the event of any complication. Population characteristics, 30-days and one-year outcomes were analyzed. Outcomes were classified according to Valve Academic Research Consortium (VARC)-2. Between 2010 and 2013, 429 patients underwent TAVI at our institution using a transfemoral (TF) access in 368 (85.7%) (Fig. 1). The proportion of patients treated via a TF approach increased from 70.1% to 89.9% ($p < 0.0001$) and the use of prior balloon aortic valvuloplasty decreased from 44.7% to 11.2% ($p < 0.0001$). We mostly used the Edwards SAPIEN XT valve ($n = 359$, 97.6%). The mean logistic EuroSCORE significantly decreased from $19.4 \pm 10.9\%$ to $15.8 \pm 8.7\%$ ($p = 0.01$). The 30-day mortality did not change significantly (6.4% vs. 5.6%,

p=0.99). Similarly, major vascular complications (12.8% vs. 15.4%, p=0.87) and stroke (2.1% vs 1.4%, p=0.75) rates remained unchanged. Two patients presented with an annulus rupture leading to death, despite a bailout valve-in-valve procedure (one case in 2011 and the other in 2013).

One patient presented with a left ventricular perforation and died at day 1. Two valve migrations occurred, requiring urgent cardiac surgery (in 2012 and 2013). Another patient had fatal periprocedural left main coronary artery occlusion. The mean length of hospital stay after TAVI significantly decreased from 8.9±11.3 to 4.8±4.7 days (p=0.002) and 72 (50.3%) patients were discharged home early within 3 days in 2013. Survival at one year has gradually and significantly improved from 2010 to 2013 (Fig. 2). This benefit is probably related to the patient profile at lower risk, as the incidence of severe complications did not change during the same period.

We report our experience of TAVI over a period of 4 years

using the Edwards SAPIEN XT valve predominantly. During this period, we observed an increase in the annual number of procedures performed in lower-risk patients. About 90% of procedures were feasible with a transfemoral approach, with a high success rate and stable and low rates of complications. Early hospital discharge is feasible in most patients. One-year survival has increased yearly since lower-risk patients were included. It is likely that the results will be further improved with the advent of the Edwards SAPIEN 3 valve.

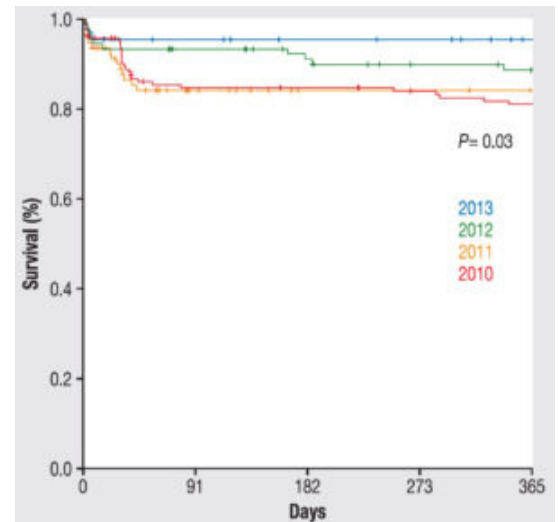


Fig. 2. Kaplan—Meier estimates of survival up to 1 year.

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