EuroIntervention 2016;11:968-970

TAVI adoption in Germany: onwards and upwards

Darren Mylotte[1]*, BCh, MD; Nicolo Piazza[2], MD, PhD; Patrick W. Serruys[3], MD, PhD

1. Galway University Hospital, Galway, Ireland; 2. McGill Healthcare Centre, Montreal, Quebec, Canada; 3. International Centre of Circulatory Health, Imperial College London, London, United Kingdom

"I am a slow walker, but I never walk back."
Abraham Lincoln

Since Professor Alain Cribier first performed a transcatheter aortic valve implantation (TAVI) in June 2002[1], TAVI has emerged as a safe, effective, and widely practised intervention that has transformed the lives of hundreds of thousands of patients worldwide[2] and has answered an unmet clinical need as TAVI is now the standard of care for inoperable patients and the preferred therapeutic option for high-risk patients with severe aortic stenosis[3,4]. Moreover, transcatheter heart valve (THV) technology has expanded well beyond Professor Cribier's initial intentions, and is frequently applied to a variety of off-label patients (intermediate/low-risk)[5], pathologies (bicuspid aortic valve; aortic regurgitation)[6], and clinical situations (valve-in-valve; valve-in-ring)[7]. The adoption of novel medical technologies such as TAVI is determined by a variety of factors, including national political and financial concerns, healthcare policy, population density and age profile, reimbursement strategies, and cultural factors[2]. In Germany, these factors seem to have aligned: Europe's most populous nation has implanted more THVs than any other nation since commercialisation in 2007[2].

In this edition of the Journal, Eggebrecht and colleagues detail the astonishing adoption kinetics of THV technology in Germany[8]. Using data derived from the independent Institute for Applied Quality Improvement and Research in Health Care (AQUA, Göttingen, Germany), these authors describe a 20-fold increase in annual THV implants between 2008 (N=637) and 2014 (N=13,264), with year-on-year implant growth of 15-25%.

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When population data are considered, Germany performs 164 TAVI cases per million inhabitants (Ireland currently performs 23 implants per million). Using restrictive evidence-based indications available in 2012, Osnabrugge et al estimated the annual number of new TAVI candidates in Germany would approximate 3,952 (95% confidence interval: 1,684-7,227)[9]; clearly, these restrictive practice patterns are not followed in Germany.

In 2008, 11,842 procedures (TAVI and surgical aortic valve replacement [SAVR]) were performed for isolated aortic valve disease in Germany. In 2014, this number had doubled to 23,217. These data, and the observation of a marginal reduction in isolated SAVR volume (5% since 2009), suggest that TAVI is actually being applied to the patient population for which it was initially intended, i.e., the 30-50% of patients denied SAVR due to advanced age, comorbid conditions, frailty, and poor left ventricular function[10]. In 2012, we estimated that only 42% of TAVI candidates in Germany actually received a transcatheter heart

**Corresponding author: Department of Cardiology, University Hospital, Galway, Ireland.*
E-mail: Darrenmylotte@gmail.com

DOI: 10.4244/EIJV11I9A198

valve[2]. Applying the implant data provided by Eggebrecht et al, and using the same restrictive indications and post-TAVI outcome data that were available in 2012, this figure increases to 109% in 2014. This estimate supports the evidence of an "indication creep" towards the treatment of lower-risk patients in Germany, as demonstrated by a gradual reduction in the logistic EuroSCORE over time. It is noteworthy, however, that the age distribution of TAVI candidates in Germany has remained constant since 2008.

Rapid proliferation of TAVI has been labelled costly and potentially detrimental to patient care[11]. Foremost among the explanations for such rapid TAVI adoption in Germany was the introduction of a diagnosis-related group (DRG)-based reimbursement system in 2010, though accumulating physician experience and patient preference for a less invasive strategy may also have driven TAVI utilisation. Moreover, the short report by Eggebrecht documents impressive reductions in TAVI-related complications, including stroke and mortality to surgical levels, despite the higher risk profile of the TAVI cohort. Such results, when applied to an elderly patient population, even one of lower risk, affirm the responsible proliferation of TAVI technology in Germany.

It is fascinating to behold that, within six years of commercialisation (2013), the number of TAVI cases (N=10,441) surpassed SAVR numbers (9,899): 50 years of surgical progress surpassed numerically in four years! What are the implications for the future of SAVR? With clear evidence of intermediate and lower-risk patients already being treated by TAVI in Germany, accumulating evidence of THV durability, and the imminent publication of randomised studies in lower-risk cohorts, it is likely that the gradual decline in isolated SAVR volumes will continue. SAVR will of course continue to play a vital role in the treatment of patients with concomitant severe coronary artery disease, infective endocarditis, and multivalve pathology. Expansion of THV technology to bicuspid aortic valve disease also remains contentious, though new-generation THVs may overcome the specific anatomical hurdles associated with this pathology[12].

Ultimately, the individual patient must remain at the centre of our treatment decisions, and, as TAVI adoption continues to expand, it should continue to be scrutinised at both local and national level, to ensure appropriate patient selection and robust clinical outcomes. Our German colleagues are to be congratulated for the widespread dispersion of TAVI technology, for treating elderly and frail patients who would otherwise remain untreated, for the excellent clinical outcomes documented in this report, and indeed for the collection of such robust data. Their efforts offer a glimpse into the future of aortic stenosis management worldwide.

Conflict of interest statement

D. Mylotte has no conflicts of interest to declare. N. Piazza is a member of the Scientific Advisory Board of Medtronic and a consultant and equity shareholder with HighLife. P.W. Serruys has no conflicts of interest to declare.

References

1. Cribier A, Eltchaninoff H, Bash A, Borenstein N, Tron C, Bauer F, Derumeaux G, Anselme F, Laborde F, Leon MB. Percutaneous transcatheter implantation of an aortic valve prosthesis for calcific aortic stenosis: first human case description. *Circulation.* 2002;106:3006-8.

2. Mylotte D, Osnabrugge RL, Windecker S, Lefevre T, de Jaegere P, Jeger R, Wenaweser P, Maisano F, Moat N, Sondergaard L, Bosmans J, Teles RC, Martucci G, Manoharan G, Garcia E, Van Mieghem NM, Kappetein AP, Serruys PW, Lange R, Piazza N. Transcatheter aortic valve replacement in Europe: adoption trends and factors influencing device utilization. *J Am Coll Cardiol.* 2013;62:210-9.

3. Adams DH, Popma JJ, Reardon MJ, Yakubov SJ, Coselli JS, Deeb GM, Gleason TG, Buchbinder M, Hermiller J Jr, Kleiman NS, Chetcuti S, Heiser J, Merhi W, Zorn G, Tadros P, Robinson N, Petrossian G, Hughes GC, Harrison JK, Conte J, Maini B, Mumtaz M, Chenoweth S, Oh JK; U.S. CoreValve Clinical Investigators. Transcatheter aortic-valve replacement with a self-expanding prosthesis. *N Engl J Med.* 2014;370:1790-8.

4. Kapadia SR, Leon MB, Makkar RR, Tuzcu EM, Svensson LG, Kodali S, Webb JG, Mack MJ, Douglas PS, Thourani VH, Babaliaros VC, Herrmann HC, Szeto WY, Pichard AD, Williams MR, Fontana GP, Miller DC, Anderson WN, Akin JJ, Davidson MJ, Smith CR; PARTNER trial investigators. 5-year outcomes of transcatheter aortic valve replacement compared with standard treatment for patients with inoperable aortic stenosis (PARTNER 1): a randomised controlled trial. *Lancet.* 2015;385: 2485-91.

5. Piazza N, Kalesan B, van Mieghem N, Head S, Wenaweser P, Carrel TP, Bleiziffer S, de Jaegere PP, Gahl B, Anderson RH, Kappetein AP, Lange R, Serruys PW, Windecker S, Jüni P. A 3-center comparison of 1-year mortality outcomes between transcatheter aortic valve implantation and surgical aortic valve replacement on the basis of propensity score matching among intermediate-risk surgical patients. *JACC Cardiovasc Interv.* 2013;6:443-51.

6. Mylotte D, Lefevre T, Sondergaard L, Watanabe Y, Modine T, Dvir D, Bosmans J, Tchetche D, Kornowski R, Sinning JM, Theriault-Lauzier P, O'Sullivan CJ, Barbanti M, Debry N, Buithieu J, Codner P, Dorfmeister M, Martucci G, Nickenig G, Wenaweser P, Tamburino C, Grube E, Webb JG, Windecker S, Lange R, Piazza N. Transcatheter aortic valve replacement in bicuspid aortic valve disease. *J Am Coll Cardiol.* 2014;64:2330-9.

7. Mylotte D, Osnabrugge RL, Martucci G, Lange R, Kappetein AP, Piazza N. Failing surgical bioprosthesis in aortic and mitral position. *EuroIntervention.* 2013;9 Suppl:S77-83.

8. Eggebrecht H, Mehta RH. Transcatheter aortic valve implantation (TAVI) in Germany 2008-2014: on its way to standard therapy for aortic valve stenosis in the elderly? *EuroIntervention.* 2016;11:1029-33

9. Osnabrugge RL, Mylotte D, Head SJ, Van Mieghem NM, Nkomo VT, Lereun CM, Bogers AJ, Piazza N, Kappetein AP. Aortic stenosis in the elderly: disease prevalence and number of candidates for transcatheter aortic valve replacement: a meta-analysis and modeling study. *J Am Coll Cardiol.* 2013;62:1002-12.

10. Iung B, Baron G, Butchart EG, Delahaye F, Gohlke-Barwolf C, Levang OW, Tornos P, Vanoverschelde JL, Vermeer F, Boersma E, Ravaud P, Vahanian A. A prospective survey of patients with valvular heart disease in Europe: The Euro Heart Survey on Valvular Heart Disease. *Eur Heart J.* 2003;24:1231-43.

11. Van Brabandt H, Neyt M, Hulstaert F. Transcatheter aortic valve implantation (TAVI): risky and costly. *BMJ.* 2012;345:e4710.

12. Piazza N, Martucci G, Lachapelle K, de Varennes B, Bilodeau L, Buithieu J, Mylotte D. First-in-human experience with the Medtronic CoreValve Evolut R. *EuroIntervention.* 2014;9:1260-3.