Editorial

Transcatheter aortic valve implantation at institutions without cardiovascular surgery departments: many questions still linger before a paradigm shift

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According to the Euro Heart Survey, roughly one third of the patients with symptomatic severe aortic stenosis will not be treated surgically with aortic valve replacement (SAVR) mainly because of the high surgical risk or patient's preference (1). By current guidelines, transcatheter aortic valve implantation (TAVI) is the treatment of choice for inoperable (class IA) and high risk (class IIA) patients affected by symptomatic severe aortic stenosis (2). Notwithstanding, recent data suggest favourable results of transfemoral TAVI compared to SAVR also in intermediate risk patients (3-6). Moreover, trials on TAVI in low risk patients are ongoing. These data, together with the constant technologic improvement of transcatheter valve prostheses, the inherent lowering of complications and costs and the encouraging data on long term durability (7,8) will reasonably get this methodology as standard of care in the treatment of severe aortic stenosis in the upcoming years. In this case, we might foresee the need to match the increased demand by doing TAVI not only in hospital with on-site cardiac surgery (CS). To this regard, the Germany TAVI model represents a glimpse into the future and an opportunity, being the country at highest rate of TAVI per million of habitant globally. To this regard, in a recent report published in *European Heart Journal*, Eggebrecht and colleagues (9) analysed the complete 2013 and 2014 dataset from the national prospective German Aortic Valve Replacement Quality Assurance (AQUA) registry including 17,919 patients treated by transfemoral approach to assess the outcome of patients treated by TAVI in hospitals with (73 in 2013, 75 in 2014) or without on-site CS (19 in 2013, 22 in 2014). Only 7.4% of the TAVI patients [1,332] were treated at sites without CS. In-house cardiologists together with surgeons from hub hospitals composed the Heart Team for these cases. All the adverse events were self-adjudicated and self-reported by the sites, with no routine on-site monitoring or adjudication committee evaluation. An independent institute for quality assurance (AQUA-Institut, Göttingen, Germany) collected all performance and outcome measures. Patient's selection for TAVI included mainly patients at high surgical risk. However, 23% of TAVI population had a Logistic Euroscore <10% and, more interestingly, patient preference was the driving procedural indication in 26% of the study population. Patients treated in hospitals without CS were older, had higher NYHA class, greater prevalence of coronary and peripheral artery disease, permanent pacemaker, chronic obstructive pulmonary disease and neurologic events and, as such, they had an higher predicted risks for operative mortality. Notwithstanding, the rates of major intraprocedural complications were similar and very low at hospitals with and without CS departments, with the exception of new permanent pacemaker implantation rate and of aortic regurgitation grade 2 or higher, which occurred more often at non-CS hospitals (2.1% *vs.* 1%; P<0.001). The rate of in-hospital death was 3.8% for patients undergoing TAVI at hospitals without CS and 4.2% for those at hospitals with CS (P=0.4). The investigators also looked at in-hospital deaths for the composite of intraprocedural complications likely to benefit from bailout surgery (device malposition, embolization, annular rupture, aortic dissection, coronary obstruction, and pericardial tamponade) and again found no difference between groups (37.0% *vs.* 33.7%; P=0.7).

A matched-pair analysis performed in 550 patient-pairs also confirmed that non-CS and CS hospitals had similar rates of intraprocedural complications [9.2% *vs.* 10.3%; P=0.543; odds ratio (OR) 0.884] and in-hospital death (1.8% *vs.* 2.9%; P=0.234; OR 0.618). No specifics on the prostheses type used and outcome data at long-term follow-up have been reported.

Besides the inherent limitations of a self-reported registry, for which underreporting and heterogeneity in outcomes among centres cannot be excluded, and of any matched analysis, the provocative results of the AQUA foster many questions: is there a real and contemporary unmet clinical need that may justify extending TAVI at institutions without CS departments (especially outside Germany)? What should be the operator and centre caseload of hospital without CS to be considered eligible offering TAVI? Who are the potential patient candidates? Is it also effective [according to VARC-2 definition (10)] at long-term follow-up? Finally, is it cost-effective?

In Germany, the TAVI caseload at the time of this study was 164 TAVI cases/million inhabitants, more than double compared to other European countries (except Switzerland). Current consensus statement suggests that TAVI should be carried out in high volume centres, by interventional cardiologist performing at least 100 structural procedures lifetime or 30 left sided structural per year of which 60% should be balloon aortic valvuloplasty (and excluding atrial septal defect/patent foramen ovale) (11). By the AQUA Registry data, the numbers of patients undergoing TAVI at non-CS hospitals declined from 735 in 2013 to 597 in 2014, even though the number of non-CS TAVI centres increased from 19 in 2013 to 22 in 2014. Accordingly, the average TAVI caseload per hospital without CS declined over time (37 in 2013 *vs.* 22 in 2014). Only 14% (3/22) of hospitals without CS had a TAVI volume >50 cases per year in 2014. Outside Germany, the TAVI caseload is still below 50 cases per year in many TAVI centre with on-site CS, also because of financial restriction. Moreover, centres without on-site CS are likely to have started their TAVI program much later or to be even lower-volume site than those included in the AQUA registry and may still be early in the learning curve, and most of the time with the availability of only one type of valve. Furthermore, these centres are likely to remain low-volume sites (12). Finally, even though the observed incidence of hard events in AQUA registry is really low, the mortality rate is still 2%, thus very far from that of PCI, making inaccurate any parallelism with PCI programs. The reported requirement for emergency CS remains as high as 1% to 5% in literature—<1% in AQUA (13,14). Then, from a logistic point of view, performing a TAVI when the cardiac surgeon or rescue equipment is 10 km away might become a real nightmare. In perspective, when TAVI will become approved for lower-risk patients, the prompt availability of a CS back up will be even more critical. Cost-efficacy remains another important issue, considering that TAVI performed in centre without CS were and are not reimbursed both in AQUA registry and elsewhere. Beside feasibility and focusing to other end-points, we should acknowledge that no conclusions can be drawn both in term of VARC-2 device success (due to incomplete data about valve performance as well as number of prostheses per patients) and long term efficacy of performing TAVI in hospitals without on-site CS. Notwithstanding, because of the higher rates of paravalvular leak and permanent pacemaker observed in patients treated by TAVI in non CS hospitals, one may argue that long term outcome (efficacy) of the latter might be worse compared to those patients treated in centres with on-site CS.

Lastly, another important point is about the most appropriate patient to refer for TAVI in a non CS center. In AQUA registry the patient selection and the decision process was different between TAVI center with or without CS—for instance age, frailty and patients preference accounted most for performing TAVI in non-CS hospitals. To this regard, it seems more reasonable to treat by TAVI in center without CS patients at prohibitive-high risk for surgery (surgery not an option) who lives in remote rural areas, because they might be comfortable with hospitals closer to home where "their" cardiologists practise (15). In conclusion, considering the overall clinical demand but also the economical restrictions, and assuming the role of healthcare system in ensuring to every patient an easy access to the most appropriate therapy, we do not see a real patient's benefit in decentralizing a minority of TAVI procedures in lower volume centers without on-site CS. According to the guidelines, the presence of a CS on-site remains an essential component of any valve therapy program not only for the potential need to intervene surgically, but also and more importantly to maintain the highest quality possible in term of counselling, selection, periprocedural, and post-procedure care of patients with severe aortic stenosis eligible for TAVI.

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Footnote

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References

1. Iung B, Baron G, Butchart EG, et al. 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.
2. Nishimura RA, Otto CM, Bonow RO, et al. 2014 AHA/ACC guideline for the management of patients with valvular heart disease: executive summary: a report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines. J Am Coll Cardiol 2014;63:2438-88.
3. Leon MB, Smith CR, Mack MJ, et al. Transcatheter or Surgical Aortic-Valve Replacement in Intermediate-Risk Patients. N Engl J Med 2016;374:1609-20.
4. Thourani VH, Kodali S, Makkar RR, et al. Transcatheter aortic valve replacement versus surgical valve replacement in intermediate-risk patients: a propensity score analysis. Lancet 2016;387:2218-25.
5. Kodali S, Thourani VH, White J, et al. Early clinical and echocardiographic outcomes after SAPIEN 3 transcatheter aortic valve replacement in inoperable, high-risk and intermediate-risk patients with aortic stenosis. Eur Heart J 2016;37:2252-62.
6. Fraccaro C, Tarantini G, Rosato S, et al. Early and Midterm Outcome of Propensity-Matched Intermediate-Risk Patients Aged ≥80 Years With Aortic Stenosis Undergoing Surgical or Transcatheter Aortic Valve Replacement (from the Italian Multicenter OBSERVANT Study). Am J Cardiol 2016;117:1494-501.
7. Kapadia SR, Leon MB, Makkar RR, et al. 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.
8. Mack MJ, Leon MB, Smith CR, et al. 5-year outcomes of transcatheter aortic valve replacement or surgical aortic valve replacement for high surgical risk patients with aortic stenosis (PARTNER 1): a randomised controlled trial. Lancet 2015;385:2477-84.
9. Eggebrecht H, Bestehorn M, Haude M, et al. Outcomes of transfemoral transcatheter aortic valve implantation at hospitals with and without on-site cardiac surgery department: insights from the prospective German aortic valve replacement quality assurance registry (AQUA) in 17 919 patients. Eur Heart J 2016;37:2240-8.
10. Kappetein AP, Head SJ, Généreux P, et al. Updated standardized endpoint definitions for transcatheter aortic valve implantation: the Valve Academic Research Consortium-2 consensus document. Eur Heart J 2012;33:2403-18.
11. Holmes DR Jr, Mack MJ, Kaul S, et al. 2012 ACCF/AATS/SCAI/STS expert consensus document on transcatheter aortic valve replacement. J Am Coll Cardiol 2012;59:1200-54.
12. Kim LK, Minutello RM, Feldman DN, et al. Association Between Transcatheter Aortic Valve Implantation Volume and Outcomes in the United States. Am J Cardiol 2015;116:1910-5.
13. Eggebrecht H, Mehta RH, Kahlert P, et al. Emergent cardiac surgery during transcatheter aortic valve implantation (TAVI): insights from the Edwards SAPIEN Aortic Bioprosthesis European Outcome (SOURCE) registry. EuroIntervention 2014;10:975-81.
14. Griese DP, Reents W, Kerber S, et al. Emergency cardiac surgery during transfemoral and transapical transcatheter aortic valve implantation: incidence, reasons, management, and outcome of 411 patients from a single center. Catheter Cardiovasc Interv 2013;82:E726-33.
15. Torzewski J, Zimmermann O, Paula J, et al. In-hospital results of transcatheter aortic valve implantation (TAVI) in a district hospital--an approach to treat TAVI patients in rural areas. Int J Cardiol 2013;168:4845-6.

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