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Re: "Transcatheter aortic valve implantation (TAVI) in Germany 2008-2014: on its way to standard therapy for aortic valve stenosis in the elderly?" by Holger Eggebrecht et al

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Using published data from the German national performance measurement programme 2008-2014, the authors analyse some aspects (frequency, patient characteristics and outcome) of TAVI in comparison with conventional aortic valve surgery, and draw conclusions for the further use of TAVI in Germany[1].

The authors do not mention any limitations for their analysis although some relevant limitations do exist. The following limitations in particular should have been considered and may call into question the conclusions of the authors.

1. Due to the absence of a "Methods" section, the database is not clearly described, although some relevant limitations of the underlying database should have been declared.
2. The authors claim that there is no on-site data monitoring ("… using standardised electronic data entry with no on-site monitoring"). In fact there was an on-site data monitoring for TAVI in 2012 and for TAVI and conventional surgery in 2010. For a random sample of hospitals and patients with aortic valve procedures, a comparison of submitted data for the performance measurement programme and the patient records was carried out[2,3]. The analysis for 2012 showed for nine out of 20 examined items "need for improvement", the worst of three categories defined and used by the AQUA-Institute to classify data validity[3].

   The analysis for 2010 showed the remarkable result that for conventional surgery six out of 22 examined items were classified as "need for improvement". For TAVI, 14 of 22 examined items were classified as "need for improvement"[2].

   These results show that data validity for the performance measurement programme must be considered as a limitation in general, and especially for TAVI.
3. The on-site data monitoring for 2012 showed that only 37.5% of neurologic complications (cerebrovascular events) documented in the patient records were declared for the performance measurement programme (260 patient records checked, 3/8 neurologic complications documented for performance measurement)[4].

   This substantial limitation of data validity seriously calls into question the author's conclusions concerning neurologic complications.
4. Data are focused on one hospital stay only. Patients who are transferred to another hospital due to a complication (in Germany TAVI is sometimes performed in hospitals without cardiac surgery departments on-site) and die after this transfer will not appear in the mortality rate of the hospital which performed the initial procedure. The occurrence of such cases is described in a German publication, although the extent cannot be quantified[5]. Nevertheless, this limitation should have been mentioned due to its relevance for the interpretation of mortality rates.
5. The authors state that no statistical tests have been performed ("Due to the differences in baseline characteristics between the groups, no statistical analysis was performed."). Nevertheless, in the "Results" section, comparisons of these groups are made and conclusions are derived, e.g., concerning neurologic complications.

   The authors also conclude that severe complications decrease, without any statistical tests justifying these conclusions. This seems to be especially questionable regarding very rare complications such as annular ruptures, with 30 cases in 2012 and 32 cases in 2014.

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Considering the limitations of the analysis the conclusions of Eggebrecht and Mehta seem to be at least partially speculative.

Conflict of interest statement

The author has no conflicts of interest to declare.

References

1. 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.* 2015;11:1029-33.

2. AQUA 2010, AQUA-Institut Bericht zur Datenvalidierung 2010. Erfassungsjahr 2009. Stand: 29. Juni 2011. https://www.sqg.de/downloads/Themen/Datenvalidierung/Datenvalidierung_Abschlussbericht_2010.pdf (accessed 10/09/2015).

3. AQUA 2012 a, AQUA-Institut Bericht zur Datenvalidierung 2012. Erfassungsjahr 2011. Stand: 15. Mai 2013. https://www.sqg.de/downloads/Themen/Datenvalidierung/Datenvalidierung_Abschlussbericht_2012.pdf (accessed 10/09/2015).

4. AQUA 2012 b, AQUA-Institut Bericht zur Datenvalidierung 2012. Erfassungsjahr 2011. Anhang. Stand: 15. Mai 2013. https://www.sqg.de/downloads/Themen/Datenvalidierung/Anhang_Datenvalidierung_Abschlussbericht_2012.pdf (accessed 10/09/2015).

5. Hein R, Abdel-Wahab M, Sievert H, Kuck KH, Voehringer M, Hambrecht R, Sack S, Hauptmann KE, Senges J, Zahn R, Mudra H; German Transcatheter Aortic Valve Interventions Registry Investigators. Outcome of patients after emergency conversion from transcatheter aortic valve implantation to surgery. *EuroIntervention.* 2013;9:446-51.

TAVI - a true success story

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Dr Döbler hints at some of the inherent limitations of the observational German nationwide quality assurance registry (AQUA) of transcatheter aortic valve implantation (TAVI). In our short report, we were limited to 1,500 words. We are grateful for the opportunity to elaborate on this report further. It is readily accepted that the AQUA registry does not compare with the strict quality standards of randomised controlled trials (RCT) or prospective registries with routine data monitoring. Nevertheless, it is the official TAVI registry of the Federal Republic of Germany and is unique in several ways. Most importantly, participation is mandatory for all centres performing TAVI, and therefore AQUA comprises all patients undergoing this procedure in Germany, providing important insights into use in clinical practice and outcomes of TAVI. Other large-scale TAVI registries or RCTs may harbour significant bias, through selection either of the participating sites or of patients by defined inclusion criteria. For example, the German Aortic Valve Registry (GARY) reported on 3,875 TAVI patients for 2011[1], when actually 7,252 patients underwent TAVI in Germany in 2011, as documented by AQUA.

It is important to understand that AQUA issues annual reports on TAVI and aortic valve surgery (sAVR), which are officially approved by the German Federal Joint Committee, the highest decision-making body of the joint self-government of physicians, dentists, hospitals and health insurance funds in Germany. Issues concerning incompleteness of data will thus apply for every year, and equally for both TAVI and sAVR. In the light of this limitation which was inherent to both groups, the trend in the reduction of TAVI mortality and complication rates seen over recent years (10.4% mortality in 2008 to 4.2% in 2014) was far more impressive than the modest improvements in operative mortality for sAVR over the same time period (3.5% in 2008 to 2.7% in 2014). Nevertheless, we never interpreted the data to indicate that TAVI was superior to sAVR, but rather that, despite a very high comorbidity index in many patients, the associated complication rates show a steep decline and tend to approach surgical rates obtained in far healthier patients.

TAVI is a true innovation and success story of interventional cardiology. It may potentially replace sAVR in many of our patients in the future. Dr Döbler's letter suggests that TAVI is the focus of controversial discussions in Germany. We should acknowledge that these "controversial discussions" do not – at least not any more – pertain to the impressive reductions in TAVI mortality and complication rates, which are also evident from several other contemporary publications from all over the world. Numerical development of TAVI in the USA and Germany is strikingly similar, with patient characteristics, outcomes and complication rates almost superimposable[2]. Rather, these discussions concern the economic implications of the explosive TAVI growth on the German healthcare system. In view of the accumulating clinical evidence, economic discussions must not overshadow the unequivocally evident clinical benefits of medical progress for our patients. With further improvements in TAVI devices (i.e., repositionable prostheses) and growing operator experience, the safety and ease of the procedure will increase. Soon we will have the results of ongoing RCTs on intermediate surgical risk patients, expected by many to demonstrate that TAVI will compare favourably to surgery. As a consequence, it can be expected that indications for TAVI will broaden and procedure numbers will increase. It is our task as physicians to offer the best available treatment for a given disease in the light of the available evidence. It is the task of the healthcare system to make such treatment accessible, given that there is clear evidence of benefit. Restriction of TAVI to hospitals with an open heart surgery programme will not solve the problem.

Conflict of interest statement

The authors have no conflicts of interest to declare.

References

1. Hamm CW, Möllmann H, Holzhey D, Beckmann A, Veit C, Figulla HR, Cremer J, Kuck KH, Lange R, Zahn R, Sack S, Schuler G, Walther T, Beyersdorf F, Böhm M, Heusch G, Funkat AK, Meinertz T, Neumann T, Papoutsis K, Schneider S, Welz A, Mohr FW; GARY-Executive Board. The German Aortic Valve Registry (GARY): in-hospital outcome. *Eur Heart J.* 2014;35:1588-98.

2. Holmes DR, Nishimura RA, Grover FL, Brindis RG, Carroll JD, Edwards FH, Peterson ED, Rumsfeld JS, Shahian DM, Thourani VH, Tuzcu EM, Vemulapalli S, Hewitt K, Michaels J, Fitzgerald S, Mack MJ. Annual Outcomes With Transcatheter Valve Therapy: From the STS/ACC TVT Registry. *J Am Coll Cardiol.* 2015. http://content.onlinejacc.org/article.aspx?articleID=2473588

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