Real-world feasibility of the VARC-recommended multiparametric approach for the assessment of post-TAVI aortic regurgitation

Mohammad Abdelghani a, Ernest Spitzer b, Ben Ren b,c, Patrick W.J.C. Serruys d, Osama I.I. Soliman b,c,*

a Academic Medical Center, University of Amsterdam, Amsterdam, The Netherlands
b Cardiology Clinical Trials Management and Core Laboratories, Rotterdam, The Netherlands
c Thoraxcenter, Erasmus University Medical Center, Rotterdam, The Netherlands
d The International Centre for Circulatory Health, NHLI, Imperial College London, United Kingdom

For a diagnostic test to be clinically useful, in addition to accuracy (i.e., representation of the true disease severity) and precision (i.e., reproducibility on rerating), it needs also to be feasible. According to Oxford dictionary, “feasible” is defined as being “possible and practical to do easily or conveniently”.

The valve academic research consortium (VARC) II-recommended multiparametric approach, although became the standard approach for aortic regurgitation (AR) adjudication after transcatheter aortic valve implantation (TAVI), is so far based on the experts’ consensus rather than on an evidence of validity. The accuracy and precision of this approach have been challenged in a handful number of studies [1, 2] but no data are available to describe its feasibility.

Between March 2012 and April 2015, 1255 consecutive 2D-transThoracic echocardiograms from five TAVI registries were provided (by 94 centers in 4 continents) to the core lab for adjudication. A total of 18 parameters of AR severity were examined in all echocardiograms for both availability and analyzability (i.e., confidence of measurement). Based on all available parameters, AR was classified as >trace in 822 studies (65.5%) and as none/trace in 433 (34.5%). Regurgitation was transvalvular in only 7%, while the remainder was paravalvular (PVL).

Among the four VARC-II criteria, parasternal short-axis view (SAX) color Doppler had the highest acquisition rate (99%) while aortic diastolic flow reversal (DFR) had the lowest (57%). All the parameters needed for regurgitation volume (RV) and fraction (RF) calculation were recorded in 66% of cases.

Out of 1240 echocardiograms with recorded SAX color Doppler, 90% were analyzable for circumferential extent (CE) of PVL jet (if present) or sufficiently reliable to exclude AR (if not present). Aortic flow modal velocity envelop from either suprasternal or subcostal view was clear enough to allow proper assessment of DFR duration and end-diastolic velocity (if applicable) in 68% of recordings. RV and RF were analyzable in 65% of recordings. While left ventricular outflow tract stroke volume was almost always feasible to assess (97%), right ventricular outflow tract (RVOT) stroke volume was the main limitation of quantitative Doppler. RVOT diameter was analyzable in 71%, RVOT velocity-time integral in 82% of recordings, and both in 68%.

Overall, a combination of VARC-II parameters was feasible in 53% of cases. In 40%, AR grading was based on a single reliable VARC-II criterion (most commonly, SAX color Doppler) supported by non-VARC parameters (color Doppler from long-axis views and continuous-wave Doppler) and in 7% of cases, AR grading was based on non-VARC parameters. AR is a common complication of TAVI [3–5] and, owing to its negative impact on clinical outcomes [3–5], it has become an end-point in TAVI trials, an important determinant of procedural success, and a benchmark used for comparing different devices and device iterations. Moreover, accumulating data on structural valve deterioration [6] at long-term further emphasize the importance of a precise judgment of AR severity and evolution. Based on currently available schemes for quantitation, basically based on the VARC-II criteria, the data on the rate, the fate and the clinical significance of AR after TAVI are considerably variable [3,5,7,8].

Our observations refer to a limited applicability of the VARC-II approach under the current acquisition practice. Our findings are consistent with signals from other core labs. In a sample of echocardiograms from the randomized PATNER trial, a consortium of core lab directors analyzed 100 studies. The consortium’s level of confidence in AR grading was high in 62 studies. Overall, 13% of post-TAVI echocardiograms were of inadequate quality for AR to be reliably adjudicated according to the VARC-recommended multiparametric approach [2]. Reasons for inability to interpret most frequently involved missing views preventing accurate interpretation of the severity of AR [2].

The VARC-III document is awaited, and for this to be more practical, it has to take into account the feasibility of the component parameters.
Sources of funding and conflicts of interest

None.

References


