Calcium load assessment for aortic valve interventions: a call for consensus

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Received 19 December 2020; accepted 31 January 2021

Keywords: Aortic valve stenosis • TAVI • Calcifications

We read with great interest the study of Kofler *et al.*[1] regarding the validation of a novel calcium score for the prediction of paravalvular leak (PVL) following transcatheter aortic valve implantation. However, we have some concerns about some critical points of the study that—in our opinion—would deserve more attention.

The first one regards the practical aspect of this high complex and time-consuming new score. Avoiding the onset of a PVL is not the only goal of the Heart Team, which must consider also many other risks (e.g. annulus rupture, stroke, conduction disturbances and survival). In our experience,[2] the receiver operating characteristics of the simpler calcium assessment—that we applied in 2016—showed an area under the curve of 0.66; the performance of the new score seems slightly better (0.71). On one hand, it could be pointed out that the more complex score is more accurate; but on the other hand, our method was more practical, and it was already proven to predict correctly also other complications.[3,4] We think this good versatility depends on the measurement of left ventricular outflow tract (LVOT)-calcifications as a continuous variable, which in Kofler's study was downgraded to a dichotomous. According to an aphorism, 'the best is the enemy of the good'. In other words, the present score seems to be well-designed to predict one specific outcome (PVL), but we are sceptical that it could be effective in predicting the others.

Secondly, we are somewhat hesitant in considering a score that has been validated without including the grade of oversizing as an input variable in the multivariate analysis. The measured outcome (i.e. PVL) is the result of an interaction between the amount of calcium, the implanted prosthesis but—much more important— 'how' this prosthesis is implanted, namely over- or undersized, as previously demonstrated.[2] This issue could explain the higher incidence of PVL that the authors found in the balloon-expandable group, which is in contrast not only with ours but also with evidences of other centres worldwide.[5] The question is not so trivial as the transcatheter aortic valve implantation interventions are always in the balance between the risk of an annulus rupture (especially in high calcified valves) and the risk of prosthesis's regurgitation, malposition up to its migration. The choice of prosthesis's size is one of the few strategic moves of the clinicians to reach a good result. This important variable is not shown in the manuscript and could have affected the performance of the score.

We are strongly convinced that the surgical and cardiological community should consider the quantitative calcium load, together with anatomical criteria, in the decision process of the Heart Team, especially in sight of the latest low-risk trials. A consensus about the right method (based on a contrast-enhanced computed tomography) is still lacking. We would like to encourage the reflection on this topic in order to provide hard and conclusive evidences in the near future that could reduce significantly the incidence of complications through a better patient's selection.[6]

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doi:10.1093/ejcts/ezab083
Advance Access publication 18 February 2021

Reply to Pollari and Fischlein

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Received 25 January 2021; accepted 31 January 2021

Keywords: Aortic stenosis • Transcatheter aortic valve implantation • Calcium scoring • Left ventricular outflow tract calcification • Paravalvular leak • Device landing zone

We thank the group for their interesting comments with regards to the proposed calcium-score to predict paravalvular leak (PVL) in patients undergoing transcatheter aortic valve implantation (TAVI).[1,2] The complexity of the new score clearly exceeds the level of previously suggested scoring systems. However, we strongly believe that the most thorough device landing zone assessment is essential to further improve functional outcomes of TAVI. This is especially important for future younger, physically more active patients. We tend to disagree with the group, that the development of a single score that could integrate the prediction of all important adverse events during and following TAVI would be preferable. Different adverse events (e.g. stroke vs pacemaker requirement) will require a completely different model of variables with potential interaction. Hence, a score focusing on one single end-point will most often outperform a scoring system with multiple adverse events incorporated. On the other hand, utilizing combined end-points might lead to high overall accuracy (area under the curve) but will be clinically less useful as discrimination between the likelihood of the individual events is hard to achieve (e.g. annular rupture vs mild PVL).[3]

The second point raised referred to the rate of PVL in relation to the amount of oversizing and type of device used. The similar rate of ≥ mild PVL in balloon-expandable (BE) and self-expandable (SE) valves found in this study as opposed to previous reports showing a higher incidence with SE valves may be explained by the institutional concept to prefer to BE valves over SE in case of more complex device landing zones, when no specific safety concerns are present. Concerning the amount of oversizing used, we fully agree that this might have an impact on both, PVL and annular rupture. Therefore, adding this variable to the score looks beneficial at first glance. However, this is technically very hard to achieve in a meaningful manner due to the following reasons. In contrast to the concept of 'theoretical oversizing' (annular area vs valve frame area), a concept of an 'effective oversizing' would have to be used in order to adjust for different valve types. This is essential, as especially with