Minimalist Approach to Evaluating Patients for Transcatheter Aortic Valve Replacement

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Transcatheter aortic valve replacement (TAVR) has become an alternative to cardiac surgery in a growing number of patients. Initially oriented to those considered high-risk or inoperable, TAVR is rapidly extending toward lower risk populations. It may not be long until most patients with severe aortic stenosis (AS) will be treated by a transcatheter approach. Undoubtedly, in this rapidly changing field, peri-procedural management will also evolve.

There is growing interest in performing TAVR using a minimalist approach. A reduction in the size of sheaths and improved delivery systems enable safer device transfer via the femoral artery in the vast majority of patients. Increasingly, centers perform TAVR in a conventional cath-laboratory setting, under conscious sedation, and without transesophageal echocardiogram monitoring. In addition, early patient discharge has become a reality. In our facility, many TAVR patients are discharged the next day, as part of a 3M protocol (Multidisciplinary, Multimodality, but Minimalist Approach). Remarkably, an anecdotal report of successful same-day discharge was recently described at another center. In this new era of high-volume TAVR procedures and long waiting lists, there is a need for a more efficient system for patient assessment. The majority of centers regularly evaluate candidates for TAVR in the cath-laboratory by performing coronary angiography with the addition of aortic root and iliofemoral assessment. In the early days of TAVR, a combination of echocardiography and invasive angiography was the foundation of patient assessment and further evaluations, such as computed tomography (CT), were ordered as needed.

The dramatic growing importance of CT angiography in TAVR is fascinating. In the original trials, cardiac CT was not requested. The main reason for performing CT in those early days was to assess the ability of the iliofemoral vessels to accommodate large caliber sheaths. The pivotal role of cardiac CT to assess the aortic root was discovered later. It is now well known that cardiac CT is crucial for TAVR sizing and prevention of paravalvular leakage and that each transcatheter device performs optimally within a specific range of oversizing degrees. In addition, cardiac CT occasionally detect adverse root features associated with annular injury or coronary obstruction and can identify important anatomic features such as leaflet fusion (ie, bicuspid aortic valve). CT may also assist in selecting an optimal projection for device implantation. As a result, cardiac CT has become an essential imaging modality before TAVR. However, few centers use the ability of ECG-gated cardiac CT to evaluate for the presence of coronary artery disease. It is reasonable to suggest that, in some cases, good quality cardiac CT can provide equally relevant information to angiography. Therefore, removing an invasive procedure from the battery of screening tests before TAVR could be feasible. In this modified screening approach, CT angiography in addition to a simple echocardiogram, may provide the heart-team with enough information to reach a decision. The safety of this modified screening, in which the step of cath-laboratory assessment is excluded, has been tested.

In this issue of Circulation: Cardiovascular Interventions, Chieffo et al describe their experience with a minimalist approach to patient screening. This Italian group has a unique practice of excluding cath-laboratory assessment before TAVR, offering a rare opportunity to evaluate the safety of this modified approach in a relatively large group of patients. The article presents a retrospective analysis of TAVR patients included in this high-volume institution. Only few patients were not evaluated by CT before TAVR, because of advanced renal failure or cardiac tachyarrhythmia’s, and were excluded. A total of 491 patients who underwent CT before TAVR were included in the analysis. The authors report that CT was interpretable in 96% of cases in which it was performed. In that facility, CT was used as a first-line imaging tool for coronary artery disease screening. A total of 375 patients were assessed without cath-laboratory evaluation and by CT only. Invasive coronary angiography screening in the cath-laboratory was performed in 116 patients, when evaluation of coronary anatomy on CT was insufficient or when significant CAD was suspected. The most common reason for sending the patient to cath-laboratory evaluation was a suspected critical coronary lesion according to CT, which was identified in 65 patients. Less than half of these patients were found to have on cath-laboratory assessment a coronary lesion deemed hemodynamically significant (n=31) and only a portion of them required coronary intervention (n=22; 4.5% of the total group of patients).

Comparison of the group of patients that underwent TAVR using the modified minimalist screening approach with the control group (those that had cath-laboratory assessment before
TAVR) showed comparable periprocedural myocardial infarction rates and similar major adverse cardiovascular events in short-term and in 1-year follow-up. In addition, no additional risk was attributed to the modified screening approach in multivariable analysis, adjusting for differences between groups. An important finding was a shorter overall in-hospital stay in the group that did not have cath-laboratory screening. That difference was a result of shorter pre-TAVR hospital stay.

A significant limitation of retrospective study by Chieffo et al is that it is not designed or powered to test the hypothesis that modified TAVR screening, that excludes cath-laboratory evaluation, is safe in patients who have a good quality cardiac CT. In addition, being a single center analysis, its results may not be applied to other centers. The optimal method of evaluation should be multicenter randomization between routine cath-laboratory assessment and selective invasive angiography. However, that kind of trial is difficult to generate. Nevertheless, the current trial provides a good indication for safety that should be further tested in future trials.

Potential advantages of this modified screening approach are numerous. Patients with severe AS are commonly frail and many of them have multiple comorbidities. It is clear that an invasive procedure in these patients may be associated with a non-negligible risk. Even if we ignore the effects of contrast load and the remote possibility of complications occurring during cath-laboratory assessment, it is obvious that the consequences of prolonged bed rest and physical deconditioning should not be underestimated. Not to mention the potential injury to the same vessel intended to be used later during the TAVR procedure. In addition, length of hospital stay is increasingly becoming a focus for many programs and direct versus indirect TAVR costs are a major issue. By excluding recovery time after cath-laboratory assessment and shortening overall hospital stay (as revealed in this analysis), TAVR may become more cost-effective. This may further improve access to TAVR technology. The modified approach may also shorten the assessment time for TAVR in symptomatic, elderly patients and help reduce the long lists of accepted candidates and being more conservative with resources such as angiography, which other patients anticipate. The dismal prognosis of patients with untreated severe AS is known for decades and hence death of a patient on a waiting list is unacceptable. Using this new screening approach, patients will be scheduled for a simple echocardiogram, cardiac CT, an office visit, and after team discussion of acceptance, will be referred for their first invasive procedure: TAVR.

This minimalistic screening method is not without limitations. The basic concept behind our ability to exclude cath-laboratory assessment before TAVR is that CT can provide all the data needed for optimal decision making. This is not definitive. The protocol required from the CT should be dedicated, including assessment of the aortic root, coronaries, and iliofemoral vessels. Optimal images are required. In addition, the approach of using cardiac CT for noninvasive coronary evaluation before valve intervention is well described but has not gained popularity. Many centers continue to assess patients before various conventional cardiac surgeries using invasive coronary angiography. In addition, coronary calcification is common in these elderly AS patients. This may decrease ability to accurately analyze images and exclude lumen narrowing.

Nevertheless, diagnosis of distal small vessel narrowing in candidates for TAVR is usually not clinically relevant. The aim in coronary assessment in candidates for TAVR is to exclude major vessel flow limiting narrowing that may be better treated before or during valve implantation. Fortunately, the negative-predictive value of currently used CT protocols in assessing large coronary vessels is high. Moreover, any concern about a specific segment of the coronary vasculature could be managed by shifting back to the conventional screening method of invasive cath-laboratory assessment. In these cases coronary angiography could be performed either days before TAVR or just before attempting TAVR, when the patient is already on the cath-laboratory table. In summary, clinical implications that could be taken from emerging data are that in this dynamic field of TAVR, invasive cath-laboratory assessment should not be viewed as a crucial step in patients' evaluation. Screening process should be patient-tailored. Specific patient populations, such as those with symptoms potentially related to coronary disease, may be approached with conventional coronary angiography at an early stage. Only time will tell what will be the optimal strategy for the evaluation of patients with severe AS. A minimalistic approach includes several advantages, however cardiologists must continue working closely with radiologists to further test the safety of bypassing cath-laboratory assessment in candidates for TAVR.

Disclosures

Dr Dvir is a consultant to Edwards Lifesciences and Medtronic.

References


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