Expanding the applications of transcatheter aortic valve replacement: Wave of the future, or not so fast?

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Central Message

The safety and feasibility of TAVR in patients with previous mitral valve surgery has been well demonstrated, but further risk stratification with regard to permanent pacemaker insertion is needed.

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In this issue of the *Journal*, Greason and colleagues¹ report their experience with transcatheter aortic valve replacement (TAVR) in patients who had previously undergone mitral valve surgery (mitral valve replacement, $n = 4$ patients; mitral valve repair, $n = 4$ patients). The increasing acceptance of TAVR as an alternative to high-risk surgical aortic valve replacement (SAVR) has been supported by the Placement of Aortic Transcatheter Valves trial (PARTNER) and subsequent related studies.^{2,3} Investigators have sought to expand the indications of TAVR to apply it to increasingly more difficult and complex situations, such as in patients with severe aortic stenosis and previous mitral valve surgery.⁴ Avoiding a reoperative sternotomy would significantly reduce the surgical risk, especially in elderly patients with a high frailty index and major preexisting comorbidities. At issue, however, is whether the previous mitral valve prosthesis might somehow interfere with the transcatheter procedure or whether the mitral prosthesis would itself somehow be adversely affected by the TAVR. Soon and colleagues⁵ raised concerns regarding the possibility of valvuloplasty balloon shifts being caused by the bioprosthetic strut or the mechanical valve pivot guards, leading to malpositioning during transcatheter aortic valve deployment and to valve dysfunction. Complications reported in previous case studies related to underexpansion of the transcatheter valve prostheses^{6,7} were among the concerns that Greason and colleagues¹ had indicated regarding this approach. Possible injury to the conduction system, eventually leading to complete heart block and need for permanent pacemaker (PPM) implantation, is also a concern that should be considered. This is especially pertinent because a successful TAVR in these patients is in effect a double valve replacement (aortic and mitral valve replacement), which is a known significant predictor of postoperative complete heart block and PPM insertion (odd ratio, 11.5; $P = .027$).^{8,9} These concerns notwithstanding, Greason and colleagues¹

reported excellent outcomes, with no significant mitral or transcatheter aortic valve dysfunction, no paravalvular leakage greater than moderate, no significant transprosthetic aortic valve pressure gradient, no outcome differences between different manufacturers (CoreValve vs SAPIEN valve), no early mortality, and 100% procedural success, with follow-up extending to 1 year in duration. Of concern, however, are the 2 intermediate-term deaths of unknown causes at 0.7 years and 1.4 years, which unless proved otherwise cannot definitively be considered non-valve related in origin. Furthermore, the new PPM insertion rate, which was reportedly not significantly greater in the patients undergoing TAVR with a history of previous mitral valve surgery than in those without such a history ($P = .491$), may actually be significantly greater than thought because of the underpowering by the small sample size. When combining the 8 preexisting PPMs with the 3 new PPMs, the total number of patients with PPMs amounts to 11 of the 18 patients, or 61% of the total patients. This is not to mention, however, a whole array of already known risk factors for TAVR-associated PPM insertion, such as the amount of device landing zone calcification,¹⁰ the left ventricular outflow tract calcium below the left and right coronary cusp,¹¹ and baseline right¹² or left¹³ bundle branch block, to name just a few obvious high-profile risk factors. Considering that meta-analyses have shown significantly greater PPM insertion

rates in patients undergoing TAVR versus SAVR,^{14,15} all these issues that may come into play in addition to the existing risks should be carefully weighed when contemplating the entire spectrum of risk to benefit of performing TAVR in these cases. On a final note, the study of Greason and colleagues¹ is a retrospective review limited to 18 patients, and although safety and reproducibility were clearly demonstrated in their hands, SAVR outcomes are also reportedly excellent, warranting further studies to demonstrate sufficient evidence to stratify the application of TAVR or SAVR in patients with previous mitral valve surgery as they apply individually.

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