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http://dx.doi.org/10.1016/j.jtcvs.2014.03.032

SUTURELESS VALVES IN AORTIC STENOSIS

To the Editor:

We read with interest the article by Santarpino and colleagues[1] in which they compared minimally invasive aortic valve replacement with sutureless valves with transcatheter aortic valve implantation in a propensity-matched cohort of 37 patients in each group. They concluded that the advantages of sutureless valves are shorter procedural times (crossclamp time of 38.9 ± 13.7 minutes and cardiopulmonary bypass time of 68.9 ± 20.2 minutes) and less paravalvular leak relative to transcatheter aortic valve implantation. They reported a high incidence of permanent pacemaker implantation (10.8%). The incidence of paravalvular leak with sutureless valves in the literature varies from 2% to 15%.[2,3] Santarpino and colleagues attributed their low paravalvular leak to "moderate decalcification."

To produce superior results to transcatheter aortic valve implantation in high-risk patients, first, zero paravalvular leak with fairly large prosthesis size and effective orifice area and low pacemaker implantation rate are required. These conditions will not be met by moderate or even less decalcification of the annulus. Second, cardiopulmonary bypass is the key contraindication to surgery for elderly patients, particularly those with pulmonary dysfunction, not the duration of bypass and clamp time. The bypass and clamp times achieved by Santarpino and colleagues[1] with sutureless valves are not too different from our own propensity-matched series[4] of 205 patients (crossclamp time of 49 minutes with a range of 42-63 minutes and cardiopulmonary bypass time of 71 minutes with a range of 59-94 minutes) in which we used minimally invasive incision but with valve sutures. Even in reoperative minimal access aortic valve replacement (with or without concomitant procedures) with standard suturing techniques, fairly short crossclamp times can be achieved.[5]

Very good applications of sutureless valves would be for a patient with a failing homograft with a severely calcified annulus and also for difficult reoperations when the annulus has been destroyed.

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http://dx.doi.org/10.1016/j.jtcvs.2014.03.005

SUTURELESS VERSUS TRANSCATHETER AORTIC VALVE IMPLANTATION: AN UNRESOLVED DILEMMA

To the Editor:

We wish to thank Dr Soppa for his comments on our study published in the February issue of the Journal.[1] His contribution helps to keep alive the debate on the most appropriate treatment strategy for high-risk patients with severe aortic stenosis.

We acknowledge that our study had several limitations, as was stated in the discussion, including a lack of randomization and failure to consider relevant factors such as patient frailty.

The main advantage of sutureless aortic valve replacement versus transcatheter aortic valve implantation is the lower or nil rate of paravalvular leak, which has also been confirmed by other investigators,[2] and not a shorter cardiopulmonary bypass time, such as suggested by Dr Soppa. This finding is of particular relevance given the well-recognized correlation between even mild paravalvular leakage and increased mortality during follow-up.[3] We congratulate Soppa and colleagues for the results they presented at the last Society for Cardiothoracic Surgery Congress showing similar aortic crossclamp times in minimally invasive surgery using a stented prosthesis. Recently, we demonstrated that in patients undergoing isolated aortic valve replacement, the aortic crossclamp times were reduced by 40% when a minimally invasive approach was

performed.[4] Soppa and colleagues might, therefore, achieve even better surgical results using the sutureless technique with significant improvement in patient outcomes.[5]

We fully agree with Dr Soppa that sutureless aortic valve replacement is an ideal option for redo surgery, such as was recently suggested by our preliminary data in this patient subset.[6]

We believe that sutureless aortic valve prostheses have the potential to shorten the surgical time, and future research will determine whether this advantage will also translate into better outcomes in high-risk patients. Sutureless aortic valve replacement has been shown to be associated with improved survival compared with transcatheter aortic valve implantation, owing to the lower or no rates of residual aortic regurgitation. Only randomized prospective studies comparing the 2 surgical techniques will allow definite conclusions to be drawn regarding this issue.

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Reply to the Editor:

With all due respect to the clinical competence of Drs Delaere and Van Raemdonck, we would like to address their pointed critique as not only unsubstantiated but also demonstrably false, which is both disturbing and damaging to the field of tracheal transplantation.[1]

The most disturbing comment is "more than half of the patients died within a 3-month period."[1] This is incorrect. Of our first 9 clinical applications using a natural scaffold, only 1 died within the short-term period, and the death was unrelated to the transplantation. A report detailing these cases is under review for publication. We can firmly suggest tissue-engineered tracheal replacement is not "destined to fail" as evidenced by survivors beyond 67 months.[2]

Second, the editorial states "Tracheal bioengineering was not tested in animal models," which is untrue, based on our previous publications. In fact, in 1994, we described the surgical technique for, and revascularization of, tracheal allotransplantations in pigs, published in this Journal.[3] To avoid immunosuppression, several large and small animal models and in vitro airway transplantation studies, not requiring immunosuppression were then completed and published in peer-reviewed journals (the number exceeded the reference limit). All have supported the readiness for ethical clinical application. Additionally, advances in neoangiogenesis, epithelial differentiation, stem cell biology, and systemic and in situ regenerative processes have been reported.[4,5] From this sound preclinical evidence, human airway transplantation has been approved by national and local regulatory bodies in 6 countries, including the US Food and Drug Administration, widely regarded as the world's toughest regulatory body.

Finally, Delaere and Van Raemdonck suggested "dissemination of misinformation" could be avoided with "clear visualization of the trachea." Video endoscopy, high-resolution computed tomography scan images, and photomicrography of the regenerated respiratory epithelium, 5 years after transplantation and without an airway stent in place have, in fact, been published,[2] and whose evidence cannot be disputed.

We value the comments of Delaere and Van Raemdonck and other leaders in this field. We do not expect undisputed acceptance of our approach; however, we would appreciate a certain degree of collegiality and respect for our unceasing efforts to push for an innovative and scientifically sound solution for a vexing clinical problem. The trachea is "one of the most difficult organs in the human body to replace." Rebuilding an identical copy of the native airway might not be possible; however, creating an ideal, nonimmunogenic replacement is. The best strategy for replacement and regeneration has yet to be determined. Tissue-engineered tracheal transplantation is still in its experimental phase, far from routine clinical application, and awaits the results of an ongoing clinical trial (www.clinicaltrials.gov). However, the assertions that our preclinical and translational advances in tracheal transplantation are "misleading and unrealistic" are overreaching, given the extensive published data supporting the cells-to-bioartificial scaffold interactions and documented long-term survival of our own patient series.

Finally, the editorial questions whether the trachea is really the first bioengineered organ. This claim has never been made by us, but rather in