Acta Cardiol Sin 2017;33:350–352
Editorial Comment
doi: 10.6515/ACS20170707A

Transcatheter Aortic Valve Implantation in Taiwan: Still Evolving!

Wei-Hsian Yin

In the current issue of *Acta Cardiologica Sinica*, Chen et al. reported the transcatheter aortic valve implantation (TAVI) experience of the first 100 cases (mean age of 81 years and mean Logistic EuroSCORE of 21.5%) in their institution. Two different TAVI devices were implanted via various vascular accesses across a long time frame of 6 years, from 2010 to 2016. The authors reported no procedural death and a high device success rate of 95%, accompanied by low rates of complications, including stroke, major vascular complications, and the need for permanent pacing. The 30-day and 1-year all-cause mortality rates were 4% and 14%, respectively. By multivariate analysis, non-transfemoral access and advanced chronic kidney disease were independent predictors of 1-year mortality.[1]

During that period of time, TAVI has transformed the treatment of valvular aortic stenosis (AS) worldwide. Initial pivotal trials tested this new technology in surgically inoperable patients, followed by high-risk surgical patients. The results were stunning. There was a significant reduction in mortality of the inoperable cohort. In the high-risk cohort, TAVI was non-inferior to surgery.[2,3] Therefore, the European and American guidelines both recommended TAVI for inoperable and high-risk patients.[4,5] With increasing operators' experience and continuous technical refinements of the devices and of the delivery systems, today, a shift towards lower-risk patients is currently taking place. The extension of clinical indications for TAVI to the intermediate-risk population was supported by the results of recent studies suggesting noninferiority of TAVI in comparison with surgical aortic valve replacement (SAVR).[6,7] Actually, transfemoral TAVI might be associated with a survival benefit in intermediate-risk patients with severe AS.[6] In the 2017 ACC Expert Consensus Decision Pathway for Transcatheter Aortic Valve Replacement in the Management of Adults with Aortic Stenosis, a Heart Valve Team is recommended to be involved with all aspects of the decision-making and delivery of this complex technology and TAVI is considered an acceptable alternative to SAVR in intermediate-risk patients (class IIa recommendation).[8]

The report of Chen et al. provides us an opportunity to examine how the effects of an evolution in patient selection and procedural characteristics overtime would affect clinical outcomes of high-risk AS patients undergoing TAVI in a "real-world" clinical setting. Although the authors did not demonstrate the evolution of case selection over time in their series, it is believed that, from a clinical perspective, the overall risk profile of these patients may decline over time. This is supported by the recently published Asian TAVI registry.[9] In total, 848 patients with mean Logistic EuroSCORE of 16.5 ± 12.0% were enrolled between March 2010 and September 2014 at 11 centers in 5 countries, including another two large Taiwanese TAVI centers.[9] The clinical outcomes of TAVI were favorable in comparison with those of previously published trials and observational studies. The procedural success rate was 97.5%. The 30-day and 1-year mortality rates were 2.5% and 10.8%, respectively. The rates of stroke, life-threatening bleeding, major vascular complications and acute kidney injury (stage 2 to 3) were all in single digits.[9]

Moreover, the significant decrease in mortality rate may pertain to more optimal patient selection. For example, aside from a host of cardiac (left ventricular dysfunction, severe pulmonary hypertension, and severe mitral regurgitation) and noncardiac (chronic se-

Received: July 5, 2017 Accepted: July 7, 2017
Division of Cardiology, Heart Center, Cheng Hsin General Hospital, Faculty of Medicine, School of Medicine, National Yang Ming University, Taipei, Taiwan.
Corresponding author: Dr. Wei-Hsian Yin, Division of Cardiology, Heart Center, Cheng Hsin General Hospital, No. 45, Cheng Hsin St., Bei-Tou, Taipei City, Taiwan. Tel: 886-2-2826-1242; E-mail: yin.wh@pchome.com.tw

vere lung disease, oxygen dependency, and end stage renal disease with dialysis dependence) conditions, frailty is increasingly recognized to be a marker of procedural-related futility.[10] Although the analysis from Chen et al. did not report on the selection of frail patients across time, it is likely that the survival benefit also derived from selecting fewer patients harboring features linked with TAVI-related futility over time. It is believed that further improvements in TAVI-related outcomes are likely to arise following ongoing refinement in patient selection, such as integrating TAVI-related risk scores during patient evaluation.[11-13]

Increasing operator/center experience is known to correlate with improved procedural outcomes during TAVI.[14,15] However, the increasing operator/heart team experience is frequently mixed with significant improvements in transcatheter valve technology, making it difficult to estimate the real effect of the learning curve on TAVI outcomes. Moreover, a number of procedural characteristics did evolve over time, including less post-dilation, a greater number of "fully percutaneous" procedures and minimalist approach (57% of Chen's cases were performed under local anesthesia), etc., which may also significantly affect their clinical outcomes over time.[16] Although the authors were using essentially the same valve and sheath type and size during the study period in most of their cases, the good clinical outcomes may reflect both the effects of the learning curve during a relatively "constant" procedural environment and the evolution of transcatheter valve technology and procedural characteristics.

Other major evolutions of TAVI procedures may also contribute to the low rates of complications in the current study by Chen et al. Newer imaging algorithms, especially on the basis of 3-dimensional computed tomography aortic annulus measurements, have changed the way in which operators choose the correct valve size.[17] As operator experience grew, these aspects likely played a key role in lowering paravalvular regurgitation rates. Also, the learning curve associated with the use of a fully percutaneous closure (vs. surgical cut-down) during the study period may have reduced the vascular complication rates. Moreover, a high implantation strategy as recommended by Chen et al. and others is of paramount importance in reducing the incidence of conduction disturbance and the need for permanent pacemaker implantation.[1,18]

In conclusion, ever since its first introduction in 2002, TAVI has matured as a stable and safe procedure. This treatment has recently been extended to individuals at lower risk. The advent of newer-generation and more slender device iterations coupled with optimized patient selection are already resulting in dramatically lower complication rates compared with earlier TAVI results. This led to the United States Food and Drug Administration's approval of low-risk clinical trials, which will answer the question regarding the durability of TAVI devices.[19] If the results of these trials are positive, it is plausible that TAVI would ultimately evolve toward younger, lower-risk patients and could become a viable alternative treatment for most AS patients. Since these newer-generation devices are expected to be launched in Taiwan very soon, in the foreseeable future, the next phase of TAVI evolution in Taiwan will be exciting.

REFERENCES

1. Chen YH, Chang HH, Chen PL, et al. Procedural characteristics and outcomes of transcatheter aortic valve implantation: a single-center experience of the first 100 inoperable or high surgical risk patients with severe aortic stenosis. *Acta Cardiol Sin* 2017; 33:339-49.
2. Leon MB, Smith CR, Mack M, et al. PARTNER Trial Investigators. Transcatheter aortic-valve implantation for aortic stenosis in patients who cannot undergo surgery. *N Engl J Med* 2010;363: 1597-607.
3. Smith CR, Leon MB, Mack MJ, et al. PARTNER Trial Investigators. Transcatheter versus surgical aortic-valve replacement in high-risk patients. *N Engl J Med* 2011;364:2187-98.
4. Joint Task Force on the Management of Valvular Heart Disease of the European Society of Cardiology (ESC), European Association for Cardio-Thoracic Surgery (EACTS); Vahanian A, Alfieri O, Andreotti F, et al. Guidelines on the management of valvular heart disease (version 2012). *Eur Heart J* 2012;33:2451-96.
5. Nishimura RA, Otto CM, Bonow RO, et al. American College of Cardiology/American Heart Association Task Force on Practice Guidelines. 2014 AHA/ACC guideline for the management of patients with valvular heart disease: a report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines. *J Am Coll Cardiol* 2014;63:e57-185.
6. Leon MB, Smith CR, Mack MJ, et al. PARTNER 2 Investigators. Transcatheter or surgical aortic-valve replacement in intermediate-risk patients. *N Engl J Med* 2016;374:1609-20.
7. Thourani VH, Kodali S, Makkar RR, et al. Transcatheter aortic valve replacement versus surgical valve replacement in intermediate-risk patients: a propensity score analysis. *Lancet* 2016;387:

2218-25.
8. Otto CM, Kumbhani DJ, Alexander KP, et al. 2017 ACC expert consensus decision pathway for transcatheter aortic valve replacement in the management of adults with aortic stenosis: a report of the American College of Cardiology Task Force on Clinical Expert Consensus Documents. *J Am Coll Cardiol* 2017;69:1313-46.
9. Yoon SH, Ahn JM, Hayashida K, et al. Clinical outcomes following transcatheter aortic valve replacement in Asian population. *JACC Cardiovasc Interv* 2016;9:926-33.
10. Green P, Arnold SV, Cohen DJ, et al. Relation of frailty to outcomes after transcatheter aortic valve replacement (from the PARTNER Trial). *Am J Cardiol* 2015;116:264-9.
11. Iung B, Laouenan C, Himbert D, et al. Predictive factors of early mortality after transcatheter aortic valve implantation: individual risk assessment using a simple score. *Heart* 2014;100:1016-23.
12. Arnold SV, Reynolds MR, Lei Y, et al. Predictors of poor outcomes after transcatheter aortic valve replacement: results from the PARTNER (Placement of Aortic Transcatheter Valve) trial. *Circulation* 2014;129:2682-90.
13. Seiffert M, Sinning JM, Meyer A, et al. Development of a risk score for outcome after transcatheter aortic valve implantation. *Clin Res Cardiol* 2014;103:631-40.
14. Nuis RJ, van Mieghem NM, van der Boon RM, et al. Effect of experience on results of transcatheter aortic valve implantation using a Medtronic CoreValve System. *Am J Cardiol* 2011;107:1824-9.
15. Arai T, Lefevre T, Hovasse T, et al. Evaluation of the learning curve for transcatheter aortic valve implantation via the transfemoral approach. *Int J Cardiol* 2015;203:491-7.
16. Babaliaros V, Devireddy C, Lerakis S, et al. Comparison of transfemoral transcatheter aortic valve replacement performed in the catheterization laboratory (minimalist approach) versus hybrid operating room (standard approach): outcomes and cost analysis. *JACC Cardiovasc Interv* 2014;7:898-904.
17. Binder RK, Webb JG, Willson AB, et al. The impact of integration of a multidetector computed tomography annulus area sizing algorithm on outcomes of transcatheter aortic valve replacement: a prospective, multicenter, controlled trial. *J Am Coll Cardiol* 2013;62:431-8.
18. Petronio AS, Sinning JM, Van Mieghem N, et al. Optimal implantation depth and adherence to guidelines on permanent pacing to improve the results of transcatheter aortic valve replacement with the Medtronic CoreValve System: The CoreValve Prospective, International, Post-Market ADVANCE-II Study. *JACC Cardiovasc Interv* 2015;8:837-46.
19. Sondergaard L. Time to explore transcatheter aortic valve replacement in younger, low-risk patients. *JACC Cardiovasc Interv* 2016;9:2183-5.