Korean Circ J. 2018 May;48(5):427-429
https://doi.org/10.4070/kcj.2018.0095
pISSN 1738-5520·eISSN 1738-5555

kcj
Korean Circulation Journal

Editorial



# Good Patients Make Favorable Clinical Outcome: K-TAVI Registry Reports

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▸ See the article "Trends and Outcomes of Transcatheter Aortic Valve Implantation (TAVI) in Korea: the Results of the First Cohort of Korean TAVI Registry" in volume 48 on page 382.



**Received:** Apr 3, 2018
**Accepted:** Apr 13, 2018

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**Conflict of Interest**
Hong MK is a clinical proctor for Medtronic.

**Author Contributions**
Conceptualization: Kim C, Hong MK; Supervision: Hong MK; Writing - original draft: Kim C, Hong MK; Writing - review & editing: Kim C, Hong MK.

Aortic stenosis (AS) is an important part of public health because it is one of common consequences in atherosclerosis and results in very poor prognosis. The prevalence of AS increases with age and its burden is expected to increase due to the aging of the general population in the developed world. Patients with symptomatic severe AS without undergoing valve replacement have a dismal prognosis, with an expected survival of 2 to 3 years. Although surgical aortic valve replacement (SAVR) is the definitive therapy for patients with severe symptomatic AS, the proportion of untreated patients is increasing because of old age and frailty associated with chronic and advanced medical conditions. Transcatheter aortic valve implantation (TAVI) is now recognized as a valid option in patients with inoperable or high-risk for SAVR. The first TAVI was performed by Cribier in 2002, it was proposed as an alternative option for inoperable or very high-risk patients. Tremendous advances in patient selection, device and procedural technology, and systematic data collection and analysis dedicated to the possibility of extended utilization of TAVI in last decade. The first randomized Placement of Aortic Transcatheter Valves (PARTNER) trial presented the value of TAVI as a durable and lifesaving treatment in high risk patients with symptomatic inoperable AS.[1)2)]

Further researches have attempted to expend the candidates for TAVI to lower-risk patients. Comparable results of TAVI to SAVR with the first-generation balloon-expandable valve and self-expanding valve[3)4)] encouraged following randomized trials to demonstrate the safety and efficacy of TAVI in intermediate-risk patients. Of these, patients were randomized to TAVI utilizing a balloon-expandable valve or SAVR in PARTNER 2A, and to self-expanding valve or SAVR in the Surgical Replacement and Transcatheter (SURTAVI) trial.[5)6)] These studies reported a non-inferiority of TAVI compared with SAVR in patients at intermediate risk, although there were differences in the pattern of adverse events associated with each procedure. International guidelines initially recommended TAVI in inoperable or high-risk patients whose life expectancy is more than one year, and the patient's quality of life is likely to improve with implantation. According to these two recent randomized trials, TAVI is recommended as a reasonable alternative to SAVR for symptomatic severe AS with intermediate surgical risk (class IIa).[7)] Furthermore, the Nordic Aortic Valve Intervention (NOTION) trial showed the safety and effectiveness of TAVI in randomly assigned lower-risk AS patients compared to SAVR in 2 years.[8)] Meanwhile, TAVI are being widely utilized even in lower risk patients. However, its value in Asian patients have not been sufficiently suggested

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in previous randomized or observational studies including very limited proportion of Asian patients. Also, there were some differences in the characteristics of Asian patients receiving TAVI compared to those in western countries.

In this issue of the *Korean Circulation Journal*, Yu et al.[9] aimed to assess and compare the procedural safety and outcome of TAVI among low- or intermediate-risk patients versus high-risk patients. Korean TAVI (K-TAVI) registry was a multicenter, non-randomized, all-comer registry of severe AS patients who performed TAVI in 17 centers in Korea. This study enrolled 576 patients from June 2015 and June 2017. Most patients underwent TAVI using transfemoral approach (98%) under general anesthesia (84%). Among the entire study population with median Society of Thoracic Surgeons (STS) score 5.2, the high-risk (STS score ≥8%) group included 200 patients, and the low- to intermediate-risk (STS score <8%) group included 376 patients. The clinical outcome was excellent with procedure success rate of 99.7% and 1-month and 1-year mortality of 2.6% and 8.9%, respectively. Patients with low- to intermediate-risk showed lower risk of all-cause death and all-cause death or disabling stroke at 1-year follow-up compared to high-risk patients. Therefore, this registry study suggests that TAVI could be an effective and safe treatment for severe AS patients with low- to intermediate-risk.

After introduction in Korea in December 2012, number of TAVI cases have been increasing for treatment of severe AS, but not as rapidly as it has been in the other developed countries. Many centers are still being in early stage for TAVI procedures and included in K-TAVI registry. Moreover, participating centers are generally using one valve or another, minority of the centers is using both valves in real world. It might have affected clinical outcomes. Additionally, current study does not show the screen failure rate. The heart team will select out patients who fit the clinical or procedural requirements of the available valves; there was no data how many patients were rejected based on undisclosed clinical factor and procedural factors such as annular size and access site requirements.

In the study by Yu et al.,[9] it is meaningful results that severe AS patients with low- to intermediate-risk have better clinical outcomes after TAVI than those with high-risk patients, given the fact that considerable low- to intermediate-risk patients are underdoing TAVI in "real-world". Even though the data in this study are not enough to support performing TAVI in all patients with low- to intermediate-risk and candidates for isolated SAVR, TAVI seems to be a good 'alternative' treatment for some patients even in low- to intermediate-risk. However, it requires careful processes for evaluation and selection of proper candidates before the procedure. Individualized and multidisciplinary approach still has a crucial role considering circumstances and outcomes in each institution. Ongoing randomized studies are expected to provide clear answers to these patients with severe AS at low risk.

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