2020 Health Technology Reassessment Report

Transcatheter Aortic Valve Replacement in Low-Risk Patients

NECA
한국보건의료연구원

Summary

Background and Purpose of Assessment

TAVR (Transcatheter Aortic Valve Replacement, hereinafter TAVR) is a procedure to percutaneously insert a stent-type artificial valve for the treatment of severe aortic valve stenosis. It was introduced as a selective reimbursement with conditions (80% co-payment rate) from June 2015 as a condition of submitting the limitation of healthcare facilities and procedure data.

The US FDA approved even the low-risk group for surgery (2019), and previous studies in Korea have also reported that a re-assessment is necessary after accumulating evidence in the future for the intermediate-low risk group (Dong-Ah Park et al., 2019). To reflect these changes and needs, the Health Insurance Review & Assessment Service commissioned the Korea Institute of Health and Medical Research to evaluate the safety and effectiveness of 「TAVR」 in patients in the intermediate-low risk group (Preliminary Benefit Evaluation Department-262 Apr. 08. 2020).

Therefore, this assessment evaluated the medical and scientific evidence for the clinical safety and effectiveness of TAVR in the low-risk group among patients with severe aortic valve stenosis.

Committee's Operation

The subcommittee consisted of a total of 7 members and held a total of three subcommittee meetings to evaluate the safety and effectiveness of the technology based on the literature for 4 months from June 26 to September 18, 2020.

Assessment Method

A systematic literature review was conducted on the safety and effectiveness of TAVR in the low-risk group, and the opinions of the subcommittee were summarized on costs and others. All evaluation methods were finalized after discussion of the "TAVR subcommittee (hereinafter referred to as the 'subcommittee').

A key question in the systematic review is "Is TAVR safer and more effective than surgical aortic valve replacement in low-risk patients with symptomatic severe aortic valve stenosis?" For the comparative procedure, the surgical aortic valve

replacement (hereinafter referred to as SAVR), a standard treatment for severe aortic valve stenosis, was selected. SAVR is a surgical procedure to replace the aortic valve with an artificial valve, and it is difficult to perform SAVR in some high-risk groups, where the risk of surgery increases due to old age and comorbidities. TAVR has begun to be used as an alternative procedure for elderly patients who are difficult to get SAVR or for high-risk surgical groups.

The literature search of a systematic literature review was conducted in three overseas and five domestic databases based on key questions. The literature selection process was independently performed by two evaluators according to the literature selection and exclusion criteria. In case of disagreement, the final articles were decided through consensus among the evaluators. The risk of bias in literature was evaluated using Cochrane's Risk of Bias, and two evaluators independently evaluated the finally selected literature. In case of disagreement, concordant results were drawn through consensus among evaluators. All data were extracted by the research unit, and if the outcome indicators of the same study were reported repeatedly, the latest literature was used for analysis. Based on the results of the systematic literature review conducted in this evaluation, the level of evidence was evaluated using the GRADE method, and the recommendation grade was determined based on the evaluation results. In addition, the literature reporting the economic outcome indicator was compiled and the opinions of the subcommittee on the cost of the procedure were summarized.

Assessment Results

The final selected literature for this evaluation was 4 studies (9 articles) reporting clinical safety and effectiveness results and 1 publication reporting economic results, for a total of 10 articles. All studies reporting clinical safety and effectiveness results were randomized clinical trials, and the total number of patients was 2,703. The average of the Society of Thoracic Surgeons operative risk score (hereinafter STS) of subjects was 1.9~3.4%.

Safety Results

Clinical safety outcome indicators were defined as 30-day mortality rate, neurological events such as stroke, myocardial infarction, atrial fibrillation, and endocarditis. As a result of a meta-analysis of safety outcome indicators, TAVR was statistically significantly safer than aortic valve replacement in terms of severe stroke and atrial fibrillation* at 1 month and severe stroke among long-term outcomes of 1 year or longer. However, there were no differences between the two groups in the other 30-day mortality rate, total neurological events,

myocardial infarction, atrial fibrillation, and endocarditis (*statistically significant result with >50% heterogeneity).

Effectiveness Results

As a result of meta-analysis on clinical effectiveness outcome indicators, TAVR was statistically significantly more effective than SAVR in terms of major bleeding* at 1 month, acute renal failure, aortic valve-related readmission, quality of life*, New York Heart Association class (hereinafter NYHA class) III or higher, and length of hospital stay. On the other hand, SAVR had a statistically significantly lower incidence than TAVR in aortic regurgitation and permanent pacemaker implantation*. Among the long-term outcomes of 1 year or more, TAVR was statistically significantly more effective than SAVR in cardiovascular-related mortality, aortic valve-related readmission, and quality of life change, whereas SAVR was statistically significantly more effective than TAVR for aortic regurgitation at 1 and 2 years and permanent pacemaker implantation at 1 year (*statistically significant result with >50% heterogeneity).

Economics-Related Results

There was a total of one document reporting economic outcome indicators, the study was conducted in Denmark, cost-utility analysis was performed using the Markov model from a social point of view. As a result, considering the cost-effectiveness threshold in Denmark, TAVR was reported as a dominant alternative with low cost and high effectiveness compared to aortic valve replacement in the low-risk group.

Conclusion and Suggestions

As a result of a systematic review of the literature, there was no difference in mortality from TAVR compared to SAVR in the low-risk group for severe aortic valve stenosis. There was no statistically significant difference between the two groups in terms of cardiovascular-related mortality, neurological events such as stroke, major vascular complications, major bleeding (life-threatening or disability), and reoperation related to aortic valves, considering the overall period. The incidence of aortic valve-related regurgitation was significantly higher in the aortic valve implantation group than in the SAVR group. In conclusion, in the low-risk group of severe aortic valve stenosis, TAVR was evaluated as a safe and effective technique because there was no difference in safety and effectiveness when compared to SAVR (GRADE reliability High).

As a result of the discussion on the reimbursement coverages according to the risk of surgery in the TAVR reassessment subcommittee, there was an opinion that the current reimbursement coverages for the low-risk group should be maintained. It is judged that the difference between TAVR cost and SAVR cost in Korea is caused by the difference in reimbursement coverages and treatment material cost. There was a consensus on the need for an increase in the cost of percutaneous aortic valve implantation and SAVR procedure and the need for an expanded reimbursement coverage according to the surgical risk criteria.

The Health Technology Reassessment Committee deliberated as “recommended TAVR for low-risk patients with severe aortic valve stenosis surgery (recommendation grade I-b)” according to Article 4, Paragraph 10 of the Health Technology Reassessment Project Management Guideline (2020. 10. 16). As a result of a systematic literature review on TAVR, the recommendation grade was determined to be 'low (grade I-b)' because it is difficult to make a strong recommendation based on the current evidence, considering that it is a technology that is not different from SAVR and expensive.

Keywords

TAVR, TAVI, Severe aortic valve stenosis, Low risk, SAVR