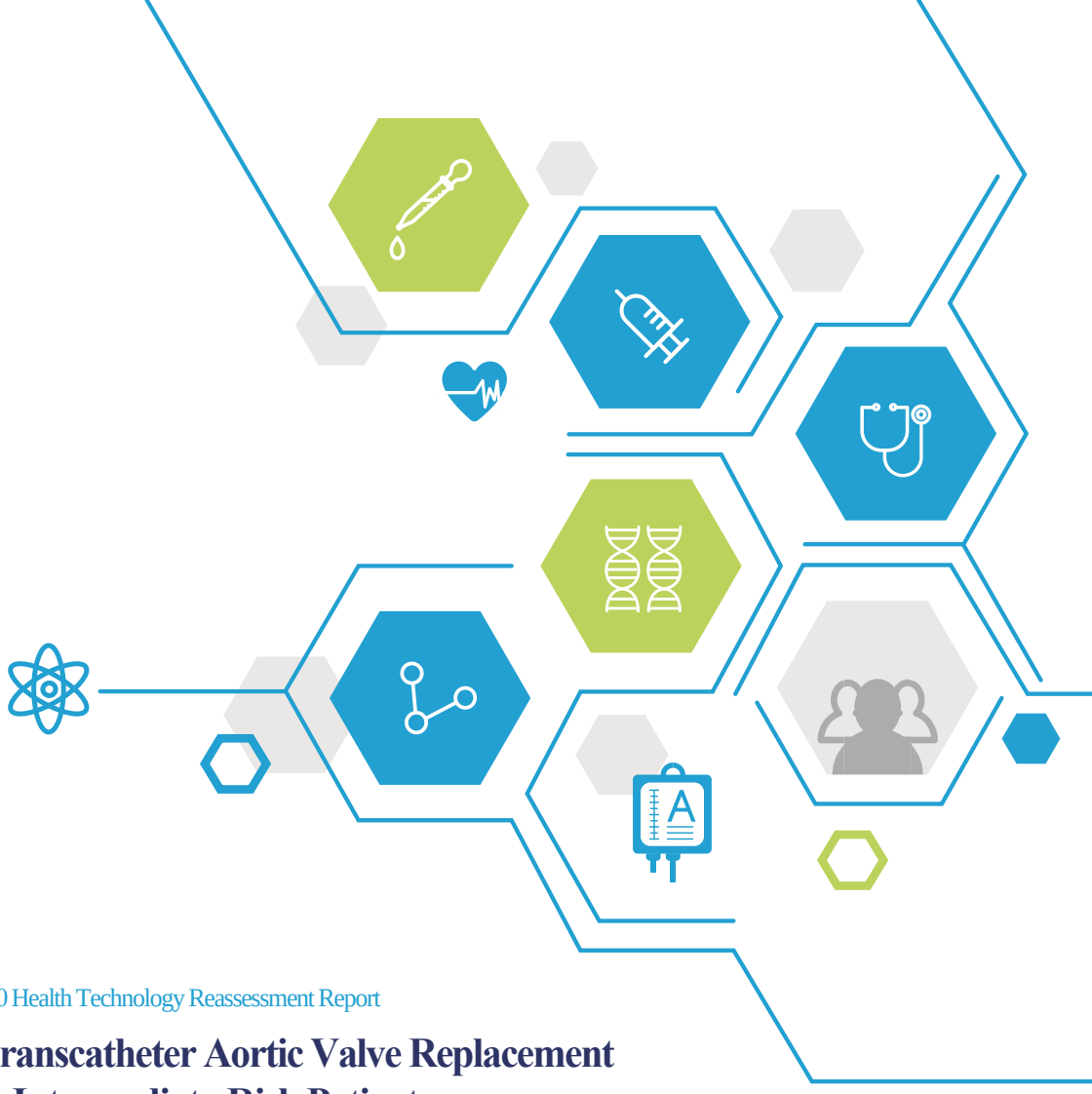

2020 Health Technology Reassessment Report

Transcatheter Aortic Valve Replacement in Intermediate-Risk Patients

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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 intermediate-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. The final deliberation was conducted on the subcommittee's assessment results of safety and effectiveness at the 10th Health Technology Reassessment Committee (2020.10.16.).

Assessment Method

A systematic literature review was conducted on the safety and effectiveness of TAVR in the intermediate-risk group, and the opinions of the subcommittee were summarized on costs and others. All assessment 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 intermediate-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. The literature selection process was independently performed by two evaluators according to the literature inclusion 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 assessment, the level of evidence was evaluated using the GRADE method, and the recommendation grade was determined based on the assessment results. In addition, the literature reporting the economic outcome index was compiled and domestic TAVR costs and related reports (Dong-ah Park et al., 2019) were summarized.

Assessment Results

The final selected literature for this assessment was 2 studies (6 articles) reporting clinical safety and effectiveness results and 7 publications reporting economic results, for a total of 13 articles. All studies reporting clinical safety and effectiveness results were randomized clinical trials (RCT), and the total number of patients was 3,692. The average of the Society of Thoracic Surgeons Operative Risk Score (hereinafter STS) of subjects was 4.4-5.8%.

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. However, there were no differences between the two groups in long-term outcomes of 1 year or longer.

Effectiveness Results

As a result of meta-analysis on clinical effectiveness outcome indicators, TAVR was statistically significantly more effective than SAVR in terms of life-threatening bleeding* at 1 month, acute renal failure, aortic valve-related readmission, quality of life*, and improvements in New York Heart Association class (hereinafter NYHA class)[1]. On the other hand, SAVR was more effective than TAVR in aortic regurgitation, aortic valve-related reoperation, and permanent pacemaker implantation*. TAVR was statistically significantly more effective than SAVR in terms of occurrence of NYHA class III or higher in the long-term outcome of 1 year or longer. On the other hand, the SAVR group was statistically significantly more effective than the TAVR group in terms of aortic regurgitation at 2 years, aortic valve-related reoperation*, and quality of life change at 1 year (*statistically significant result with >50% heterogeneity).

Economics-Related Results

There were a total of 7 documents reporting economic outcome indicators, with 3 from Canada and 1 each from Japan, France, Australia, and the US by study country. Considering the cost-effectiveness threshold of each country, three studies reported that percutaneous aortic valve insertion was a dominant alternative, which is cheaper and more effective, than aortic valve replacement.

Considering the cost-effectiveness threshold, Considering the cost-effectiveness criterion, there were three studies that reported the possibility of being cost-effective (moderate to high uncertainty). One study conducted in Japan suggested that TAVR was not cost-effective (Kodera, 2018). Cost-effectiveness was more affected by the cost difference than by the effect difference, and the factor that greatly affected the cost was the valve price of TAVR.

In addition, according to a report by Dong-ah Park et al. (2019) regarding the cost of TAVR in Korea, the out-of-pocket cost of TAVR per patient was KRW 25,914,000 out of KRW 40,981,000 per patient as of 2018, when the co-payment rate for TAVR was 80%. On the other hand, the cost of the single SAVR procedure was 22,874,000 won, which was lower than that of TAVR, and the out-of-pocket cost was 1,344,000 won, which was lower than the patient co-payment rate of TAVR.

[1] A classification tool developed by the New York Heart Association that classifies the activity and breathing-related symptoms of patients with heart disease into 4 classes

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 intermediate-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). The incidence of aortic valve-related regurgitation and aortic valve-related reoperation was statistically significantly higher in the TAVR group than in the SAVR group. In conclusion, in the intermediate-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 compared to SAVR (GRADE reliability Moderate-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 it would be appropriate to apply for the same reimbursement coverages as SAVR in the group where SAVR is impossible or high-risk, to apply 50% co-payment for the intermediate-risk group, and to maintain the current reimbursement coverages for the low-risk group. It is judged that the difference between TAVI 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 TAVI and SAVR procedures and the need for an expanded reimbursement coverage according to the surgical risk criteria.

The Health Technology Reassessment Committee deliberated as “recommended TAVR for intermediate-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, Intermediate risk, SAVR