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Original article

Cost effectiveness of transcatheter aortic valve implantation in patients with aortic stenosis in Japan

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ABSTRACT

Background: Transcatheter aortic valve implantation (TAVI) is a less invasive treatment for elderly patients with aortic stenosis. However, the cost of TAVI is a major issue. This study analyzed the cost effectiveness of TAVI in Japan.

Methods: We developed an economic model to evaluate the quality-adjusted life years (QALYs) and costs of TAVI, surgical aortic valve replacement (SAVR), and medical therapy over a 10-year time horizon from the perspective of Japanese public healthcare payers. The first model compared transapical or transfemoral TAVI with Sapien valve implantation and medical therapy in inoperable patients. The second model compared transfemoral TAVI with Sapien XT valve implantation and SAVR in operable patients with intermediate surgical risk. We assumed a cost-effectiveness threshold of 5,000,000 yen per QALY, and assessed the cost-effectiveness probability with 100,000 simulations. We performed a broad sensitivity analysis to assess the effect of uncertainty on our results.

Results: Among inoperable patients, the incremental cost-effectiveness ratio for TAVI compared with medical therapy was 3,918,808 yen per QALY. In operable patients, the incremental cost-effectiveness ratio for TAVI compared with SAVR was 7,523,821 yen per QALY. The cost-effectiveness probability of TAVI was 60% for inoperable patients and 46% for operable patients. Among inoperable patients, the cost-effective threshold of TAVI was <7,759,085 yen. Among operable patients, the cost-effective threshold of TAVI was <5,427,439 yen.

Conclusions: This study suggests that TAVI has good cost effectiveness for inoperable patients, but not for operable patients.

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Introduction

Transcatheter aortic valve implantation (TAVI) was developed for the treatment of severe aortic stenosis (AS) [1]. TAVI is a less invasive treatment than surgical aortic valve replacement, and is an effective procedure for elderly and high-risk patients [1–3]. However, the cost of TAVI is a major issue, with the Sapien valve (Edwards Lifesciences Co., Irvine, CA, USA) costing 4,530,000 yen in Japan. Cost-effectiveness analysis is a research method applied to estimate the incremental benefit and cost of a new treatment compared with the standard treatment [4]. A number of reports in Western countries have examined the cost effectiveness of TAVI [5–11]. However, their conclusions varied, with some studies reporting TAVI to be cost-effective, while others did not. Healthcare systems differ between countries, as does the cost effectiveness of TAVI. However, no cost-effectiveness analysis of TAVI has been conducted in Japan. Considering the low economic growth and burgeoning elderly population in Japan, health economic issues are increasingly important. Thus, in the present study we analyzed the cost effectiveness of TAVI in Japan.

Methods

We developed an economic model to evaluate the costs and effectiveness of TAVI. The model evaluated the quality-adjusted life years (QALYs) and cost of three treatment options—TAVI, surgical aortic valve replacement (SAVR), and medical therapy—during a 10-year time horizon from the perspective of the Japanese public

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healthcare payer. We constructed two models. The first model compared transapical (TA) or transfemoral (TF) TAVI with a Sapien valve and medical therapy in inoperable patients. We defined an inoperable patient as a patient with a 30-day mortality and morbidity rate of >50% according to one of the Placement of Aortic Transcatheter Valves (PARTNER) trials [1], which are large randomized controlled trials of AS. The second model compared TF TAVI with a Sapien XT valve and SAVR in operable patients with intermediate surgical risk. We defined an operable patient with intermediate surgical risk as a patient with a 30-day mortality rate of 4%–8% according to another PARTNER trial [3]. We derived various parameters from the PARTNER trials and the Optimized Catheter vAlvular iNtervention (OCEAN) TAVI registry [12,13], which is a Japanese TAVI registry. The analysis was performed according to the Consolidated Health Economic Evaluation Reporting Standards statement and in accordance with a Japanese guideline [4,14].

Model

We developed a Markov model with Monte Carlo simulations to evaluate the efficiency of TAVI. The structure of the model is shown in Fig. 1. A monthly cycle was modeled with each cycle, the patient may die, be hospitalized, or become stable. We defined four study phases: study entry, stability, hospitalization, and death. At the entry point, all patients were classified in the study entry phase. If the subsequent 1 month was uneventful, the patients were classified as stable. We combined stroke, myocardial infarction, and vascular complications as hospitalization conditions.

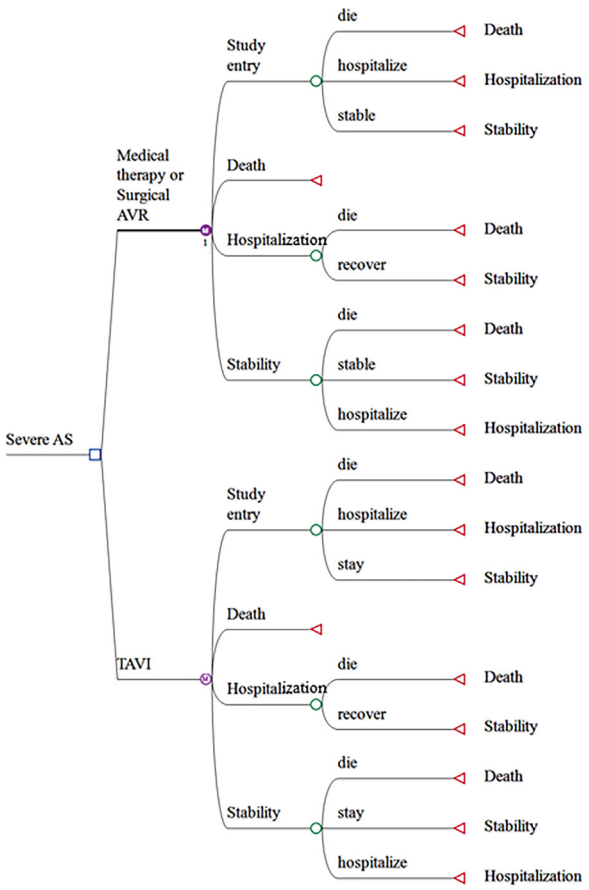

Fig. 1. Markov model of transcatheter aortic valve implantation. The model applies to each monthly cycle. AS, aortic stenosis; AVR, aortic valve replacement; TAVI, transcatheter aortic valve implantation.

Population

The population of patients in each group is shown in Table 1. Our study population reflected that of the PARTNER trials [1,3]. To compare TA or TF TAVI with Sapien valve implantation and medical therapy, we used the PARTNER cohort B, which comprised inoperable patients. The average patient age was 83 years, 46% were men, their average Society of Thoracic Surgeons (STS) score was 11, and 93% had a New York Heart Association class of III or IV [1]. To compare TF TAVI with Sapien XT valve implantation and SAVR, we used the PARTNER 2 cohort A, which comprised patients with an intermediate surgical risk. The average patient age was 82 years, 55% were male, the average STS score was 6, and 77% were New York Heart Association class III or IV [3].

Intervention vs. comparator

In the first model, we compared TA or TF TAVI with Sapien valve implantation and medical therapy in inoperable patients. With medical therapy, balloon valvuloplasty was included if necessary. In the second model, we compared TF TAVI with Sapien XT valve implantation and SAVR in operable patients with an intermediate surgical risk.

Time horizon

We restricted the time horizon to 10 years in both models. The average age of both inoperable and operable patients was approximately 82 years. We considered that a 10-year estimation would be sufficient to evaluate the cost effectiveness of the treatments. In the sensitivity analysis, we changed the time horizon to 3, 5, 10, 15, and 20 years.

Mortality and hospitalization

The mortality rates associated with each treatment are shown in Table 2. The mortality for all treatments was based on that reported for the PARTNER cohorts and OCEAN TAVI registry [12,13]. For inoperable patients, TAVI was 60% superior to medical therapy in terms of survival. For operable patients, TF TAVI was 10% superior to SAVR in terms of survival. Among patients who underwent TAVI in the OCEAN TAVI registry, the procedural 30-day mortality rate was approximately 2%. The hospitalization rate was based on the PARTNER trial. The reasons for hospitalization included worsening heart failure, stroke, and vascular complications. Among inoperable patients, the hospitalization rate was 50% lower with TAVI than with medical therapy. For operable patients, the hospitalization rate was higher with TAVI than with SAVR. We modified the mortality rate to evaluate the effects of that rate in the sensitivity analysis.

Utility

The utility value in each situation is shown in Table 2. The PARTNER study determined quality of life (QOL) using the EuroQol Five-Dimensions Questionnaire [5,15]. We used data of the PARTNER study and from other trials to define QOL [16]. In patients with AS before SAVR or TAVI, the QOL was 0.66. In patients with AS after SAVR or TAVI, the QOL was 0.75. We assumed that the QOL of hospitalized patients was 0.48. Following a Japanese guideline, we decreased the utility values by 2% annually [14].

Costs

We performed an economic evaluation from the perspective of a public healthcare payer in Japan. The costs included procedural,

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