

## Cost-effectiveness of transapical aortic valve implantation

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The rising cost of health care places a large amount of pressure on the governments of all countries to reduce other areas of spending and results in additional tax increases. In addition, clinicians must determine which therapy is more effective and identify which patients will benefit most from a given treatment in daily practice (1).

Calcific aortic stenosis (AS) is the most frequent manifestation of valvular heart disease, not only in Western countries, but also in some Asian nations, with the prevalence expected to increase as the population ages. Three percent of all adults 75 years of age have moderate to severe AS, and the condition is the leading indication for valve replacement in Europe and the United States (2). Surgical aortic valve replacement (AVR) is the preferred treatment for patients of all age groups, although it has limitations in octogenarians and nonagenarians. Open heart approaches are limited by higher perioperative risks, prolonged recovery and a poor quality of life after surgery (3).

The surgical 30-day mortality rate for nonagenarians was reported to be 17% in one contemporary series, with a 40% mortality rate by 13 months (4). Therefore, less invasive percutaneous options are needed for severe AS patients with high surgical risks. For this reason, transcatheter aortic valve implantation (TAVI) was developed. After the adoption of the retrograde approach, screening examinations of the lower limb vessels revealed that this system cannot be applied in certain patients (5). Therefore, the transapical approach was established.

In the current issue of the *Journal of Thoracic Disease*, Gada *et al.* reported that both transapical TAVI and high-risk AVR are more cost-effective than medical management. However, at the same time, these authors pointed out that transapical TAVI fails to meet accepted criteria for incremental cost-effectiveness

relative to AVR. This is an important point with respect to the latest technology that transapical TAVI may not be cost-effective over the long-term as is, because all therapy incurs costs. Interpretations of the decision-analytic model should be made very carefully, since the results may change based on outcomes. For example, the authors only briefly mentioned that the prevalence of peripheral artery disease (PAD), which was significantly higher in the transapical TAVI arm, was found to be a strong predictor of death and cardiovascular events. In addition, the majority of the patients with PAD died due to stroke or heart disease, which influenced the results obtained in the registries and clinical studies. Hence, the two cohorts in this study appeared similar in terms of cardiovascular risks; however, the increased incidence of adverse events and higher costs observed in the PAD patients during follow-up were not surprising. Therefore, more research should be directed toward PAD. In addition, a recent report revealed significantly increased costs in the PAD patients (6) enrolled in the prospective REACH Registry (4,693 patients in France and 5,594 patients in Germany). In that study, the hospitalization rate and costs due to revascularization and amputation associated with atherothrombotic disease were high in both France and Germany, especially among the patients with PAD.

The other issue that increases costs is the cost of technology, which will hopefully decrease due to the advent of second-generation devices. In addition, the mortality rate in both groups was quite high, greater than 40% within two years, although this rate was lower than that of medical management, which was associated with a mortality rate of approximately 80% within two years. Therefore, the following criticism of TAVI has been raised: "Can we continue to perform such an expensive procedure in very high-risk elderly patients whose predicted survival rate is only 60% over two years?". Of course, it depends on the country and society, which may or may not allow the government to spend such large amounts of money on a population of patients among whom 40% die within two years. However, data obtained from the PARTNER (cohort B) study showed that TAVI improves both life expectancy and the quality of life to a clinically important degree in comparison with medical therapy. Therefore, clinicians must assess the quality-adjusted life-years (QALYs) in patients with severe AS. For

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this reason, the paper by Goda *et al.* comparing two cohorts is valuable for seeking economical outcomes.

Another strength of this paper is that the authors proposed these economical outcomes from the standpoint of real-world clinical practice employing technology using registry data in order to provide better perspectives. Regarding the assessment of economics in the PARTNER cohort A, transfemoral TAVI was associated with total 12-month costs that were slightly lower than those of TAVI, with slightly higher quality-adjusted life-years (QALYs), such that transfemoral TAVI was found to be economically dominant compared with surgical AVR in the base cases and economically attractive (incremental cost-effectiveness rate <\$50,000/QALY) in 70.9% of the bootstrap replicates (7). However, the setting was a clinical trial.

The advent of TAVI has changed daily practice regarding treatment strategies for high-risk AS patients. Therefore, this procedure, particularly the transfemoral approach, should be performed, although the transapical approach is associated with higher mortality and is less cost-effective. Recently, the transaortic approach has been employed in cases in which the peripheral artery cannot be used; therefore, this procedure may be performed as a substitute in transapical TAVI patients. The authors mentioned that the annual mortality of patients who develop heart failure and stroke was not found to be significantly different than that of the patients without these conditions. Therefore, the outcomes would have been better in the transapical TAVI arm if surgical AVR and transapical TAVI were associated with a similar prevalence of PAD, since PAD had a large impact on the prognosis. In addition, the authors pointed out that transapical TAVI may provide net health benefits at acceptable costs in selected high-risk patients in this actual setting. Therefore, this technology should be applied in properly selected symptomatic populations at this time. The approach can be applied to more patients if it is improved appropriately or patient selection is changed to better apply the technology.

Second-generation TAVI devices and downsizing systems have already been implemented; thus, a decrease in the incidence of paravalvular aortic regurgitation and a reduced rate of complications are expected. These improvements will contribute to achieving better clinical results and a higher quality of life, which leads to improved QALYs.

There are difficulties in patient selection, as none of the risk scoring systems are perfectly fitted to evaluate patients with severe conditions. Therefore, clinicians must assess patients

based on frailty or visual inspection. For this reason, the use of a heart team approach is mandatory, namely that paramedical staff should also participate in assessing a patients' severity. To obtain a better QOL for the patient, clinicians must evaluate not only physical, but also spiritual factors in order to address the diverse features of the QOL and increase QALYs in a way that allows the heart team approach to be implemented.

Finally, this paper sounds an alarm with respect to the use of transapical TAVI from the standpoint of economical outcomes. However, before conducting an economic assessment, it is necessary to realize that clinical effectiveness is not an inherent characteristic of a specific treatment, but rather varies depending on the clinical features of the treated patient, particularly regarding the indication for treatment. The key to practicing cost-effective therapy is to apply treatments correctly to cases and indications for which the treatment is truly effective, because clinical effectiveness is the key to cost-effectiveness.

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