- I'm David Cohen. I'm a interventional and structural cardiologist. I work at the Cardiovascular Research Foundation in New York city and practiced at St. Francis Hospital on Long Island.

Importance of the Study

So the study that I presented at the TCT was the economic study of the PARTNER 3, randomised trial. The importance of this study is that transcatheter aortic valve replacement, TAVR, as we call it here in the United States is becoming increasingly popular. If there are more TAVRs done in the United States than surgical valve replacements now, but the valve is quite expensive. In the United States, the TAVR valve costs about $32,000 and surgical valves costs between five and $6,000. So there's quite a large price differential, and there's always been concern with the high cost of the TAVR valve, whether it's economically feasible from the standpoint of the healthcare system. And so our study was really designed to address whether TAVR compared with surgical aortic valve replacement is cost-effective for these large group of low-risk patients.

Used Data

The data that we used for this study were came directly from the PARTNER 3, randomised trial. We actually linked the patients in the randomised trial to Medicare data, which is available for the vast majority of those patients because of their age, and through the Medicare data, we were able to obtain their in-hospital costs as well as their follow-up costs for all of their medical care, including physician visits, outpatient care, hospitalizations, rehabilitation, all of those factors over a two year follow-up period.

Complexities in Relation to the Costs of TAVR vs SAVR

The factors that come into play in comparing these costs really are all of the differences and different patterns of resource utilisation. In the initial hospitalisation, TAVR is a much quicker procedure with a much shorter hospitalisation. And then we were interested in understanding of whether there were additional costs savings during the follow-up period, perhaps related to a reduction in rehospitalizations or on the contrary, of whether there was catch-up, whether the less invasive nature of TAVR and some of the complications that are a little more frequent with TAVR such as paravalvular regurgitation or pacemakers led to higher costs in the follow-up period. In addition, we wanted to understand the quality of life of these patients, which was done through patient surveys that were conducted at different time intervals over the follow-up period.

Key Findings

So the key findings of our study were several, first, the procedures were much more expensive for the TAVR patients by about $19,000. This was obviously driven by the high cost of the TAVR valve. During the remainder of the hospitalisation though, TAVR led to about four and a half day shorter hospital stays including about two days shortening of ICU stay. And that was associated with substantial cost savings. By the time the patients left the hospital, the costs were almost identical, only about $500 higher with TAVR. Then over the next two years, there were another $2,600 worth of cost savings with TAVR and this related mostly to reductions in rehabilitation and rehospitalization costs that occurred during the first six months of follow-up. Finally, there were small but important improvements in both survival or life expectancy, as well as quality of life in the early follow-up time period, leading to a gain of about 0.05 quality adjusted life years with TAVR compared with surgical aortic valve replacement. When the cost and the quality adjusted life expectancy data were combined, TAVR was an economically dominant strategy. That is, it saved money and improved outcomes for patients compared with surgical aortic valve replacement over the two year follow-up period. The cost-effectiveness ratio was highly cost-effective at a threshold of $50,000 per quality adjusted year of life gained. And 95% of replicates indicating that we are very highly confident that at least at two year follow-up, TAVR is highly cost-effective compared with surgical aortic valve replacement. These results also extend to lifetime perspective, but only if one assumes that there are no major differences in survival between the two strategies at that time, which at the present, you know, currently is not completely certain.

Patient Groups that Most Benefited from TAVR

We did a number of subgroup analysis and there were two groups that really stood out in terms of cost-effectiveness. One was patients who had New York Heart Association class three or four symptoms when they presented for their valve replacement, and the other was patients who had a Kansas City Cardiomyopathy Questionnaire score of less than or equal to 70. These are both really saying the same thing, which is that patients who had more symptoms and more disability, more functional limitations when they presented were more likely to derive a substantial economic benefit. In those two patient groups, the cost savings at two year follow-up were not just $2,000 as they were in the overall population, but actually between six and $7,000 per patient. So those two groups really stood out as being the most cost-effective uses of TAVR compared with surgical valve replacement.

Take-Home Messages

The take home messages from this study are that at least over the two-year intermediate term follow-up period, TAVR is an economically dominant strategy for these low-risk patients with severe symptomatic aortic stenosis, saving money, as well as improving quality of life, and actually providing a small gain in life expectancy for these patients. However, the lifetime cost effectiveness of TAVR is still very dependent on the long-term outcomes. If there is a modest survival benefit with surgical aortic valve replacement, then these findings would actually reverse and surgical aortic valve replacement would become much more cost-effective, but that is an area of great uncertainty, and we need to wait for the five and 10 year follow-up of the trial in order to understand those findings.

Next Steps

So the next steps are, first of all, to publish our results. So we're in the process of writing them up so people will be able to read them and understand them in great detail. And then second, most importantly, to continue to follow the same patients, which is ongoing. There will be trial follow-up at five years and the sponsor and the FDA are continuing the follow-up through 10 years now, to really understand the long-term outcomes, whether there are differences in valve durability, whether there are differences in quality of life, and whether there are differences in survival as these patients continue to live with their prosthetic valves.