Discussion

Dr Song Wan *(Shatin, Hong Kong)*. Your 2-year outcome analysis indicated excellent safety, efficacy, and hemodynamic performance of this newly developed bovine pericardial valve. I have 2 related questions and 1 comment.

While the incidence of thromboembolic events was remarkably low at 2 years, for all hemorrhage and for major hemorrhage the late linearized rate still exceeded 2 times the FDA-specified OPC rates. So comparing with the 1-year data reported last year by Dr Sabik at this meeting, these parameters showed a remarkably improved change at your analysis. Was such improvement due to reducing the use of anticoagulation and antiplatelets for the preexisting conditions as well as for the surgical aortic valve replacement prophylaxis?

Dr Francois Dagenais *(Quebec City, Quebec, Canada)*. Yes. When you look at discharge, only 50% of patients were on aspirin alone. So many were on dual antiplatelet therapy or had Coumadin therapy for other conditions. As you alluded, within the first year, major bleeding events were related to these patients who were on higher anticoagulation regimens for other comorbidities, for concomitant coronary artery bypass grafting or atrial fibrillation. At 2 years, 80% of patients were only on aspirin, thus probably explaining why this linearized rate decreased at the 2-year point.

Dr Wan. Comparing with the 1-year result, the moderate and severe PPM rate remained high if not higher. Although you indicated these findings did not affect patients' clinical outcomes, the surprising observation to me was the majority of these patients' severe PPM occurred in those who had a 23-mm or even larger size valve. And noting the discharge rate as you just mentioned, the majority of patients (more than half of the patient population) take only antiplatelets, and this rate increased to more than 75% in 2 years; even the 8.4% of patients were not taking any medication.

So in that situation, should valve thrombosis be ruled out here? Did any of these valves, particularly those with severe PPM, have been investigated by echocardiography or magnetic resonance imaging? Current American Heart Association/American College of Cardiology guidelines even propose we need to anticoagulate patients up to 6 months. Although these patients already missed the chance of early postoperative anticoagulation, would you treat them with warfarin now if there is no contraindication?

Dr Dagenais. The debate of the necessity of early anticoagulation in bioprosthetic aortic valves still remains open. The sole valve thrombosis noted in the study was with a patient in whom reduced valve leaflet mobility was observed. Anticoagulation was increased, and the thrombosis resolved with improvement in leaflet mobility. Specifically in this study, we haven't looked into leaflet thickening or other impact that could explain the PPM. The PPM issue is intriguing for sure. As you stated, two-thirds of the patients with severe PPM had a valve size 23 or larger, which is unusual with severe PPM.

To further evaluate this conundrum, we evaluated 8 patients on stress echo ergocycle and looked at the valve performance. Surprisingly, we observed a 15% increase in EOA with exercise. This increase was highly significant, showing that the Avalus valve probably has an opening reserve at exercise, thus explaining the good clinical outcomes in these patients. Thus, assessing valve performance at rest especially for the Avalus valve seems suboptimal. For sure, further studies at exercise are required to confirm this hypothesis.

Dr Wan. My final comment relates to the patient population in your study. For any new valve prosthesis with advanced anticalcification treatments, whether it translates to improved durability would always be the primary concern for most surgeons, but for your study the patients' mean age was more than 70 years. So in that particular subgroup of patients according to the current available literature, life expectancy after aortic valve replacement in North America is approximately 10 years. With this in mind, the current study wouldn't be able to study the durability issue, although I understand that may not be designed in the first place.

Dr Dagenais. Yes, I totally agree with you that it is difficult to assess long-term durability in an older population. On the other hand, this cohort will be followed prospectively up to 10 years, thus suggesting a good picture of the valve durability in this age group. The patients randomized in this trial are similar to those in other FDA valve-related trials. In the event the midterm outcomes are good, extending use to younger patients may be considered and results ideally assessed by prospective registries.