Mid-term follow-up after transcatheter aortic valve implantation

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This editorial refers to ‘Transcatheter aortic valve implantation: 3-year outcomes of self-expanding CoreValve prosthesis†, by G.P. Ussia et al., on page 969

The prognosis for patients with symptomatic aortic stenosis is poor. Although open surgical aortic valve replacement (SAVR) is the gold standard for the management of aortic stenosis, there are no randomized trials or formal evaluations of the sort that would currently be the norm to gain approval of such a costly and invasive treatment. However, like the use of parachutes when jumping from airplanes, randomized trials were presumably looking for. Fortunately, the great majority of these are mild or moderate. On average, most patients have less paravalvular aortic regurgitation than they had valvular regurgitation prior to their procedure. Admittedly we may not fully appreciate the long-term effect of moderate regurgitation. Although this is a minor consideration in elderly patients, this may become an issue if TAVI is applied in younger and lower risk patients. More importantly, paravalvular leaks sometimes can be severe. In the study of Ussia et al., persistent severe leaks were not observed, although it is worth noting that almost one in five patients required some sort of intervention on the implanted valve (dilation, repositioning, or a second valve). Such interventions may not be without consequences.

Are transcatheter heart valves (THVs) durable? Yes, so far. All prosthetic cardiac valves are required to undergo prolonged accelerated wear testing and failure mode analysis. However, there is no substitute for clinical experience. Prior experience with surgical valves demonstrates that the 10–20 year durability anticipated with some valves is often not achieved with other valves. We have reasonable clinical documentation of 3 year durability with the SAPIEN valve and now with the CoreValve bioprosthesis. Concerns about early leaflet deterioration, frame fracture, and instability have been largely allayed. However, late follow-up beyond 5 years remains relatively sparse and is not yet adequate to support use in patients who are good candidates for surgery.

Is the TAVI procedure inherently more dangerous than medical management? Initially yes, but this early procedural risk is soon overwhelmed by the later survival and functional benefits. In the PARTNER 1B trial of patients considered too high risk for surgery, there was an absolute 20% reduction in mortality at 1 year as compared with medical management, with survival curves continuing to diverge out beyond 2 years.

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Is the TAVI procedure more dangerous than SAVR? In the PARTNER 1A high risk trial, TAVI (transarterial and transapical groups combined) was ‘non-inferior’ to SAVR. However, if one looks more closely at the transfemoral procedure, TAVI actually bested SAVR, with a mortality that was less than half that with surgery (3.7 vs. 8.2% 30-day mortality as treated, $P = 0.05$).\textsuperscript{7} TAVI outcomes were particularly favourable in the randomized PARTNER trials.\textsuperscript{7,12} This was particularly so given a very early TAVI surgery (3.7 vs. 8.2% 30-day mortality as treated, bested SAVR, with a mortality that was less than half that with groups combined) was ‘non-inferior’ to SAVR. However, if one PARTNER 1A high risk trial, TAVI (transarterial and transapical procedure in the hands of very experienced surgeons). In the Italian registry,\textsuperscript{2} the Society of Thoracic Surgeons (STS) predicted risk of surgical mortality score was almost identical to that seen in the contemporaneous PARTNER trials; however, transarterial TAVI procedural mortality was higher (11.2%, vs. 5% and 3.7% in the Italian registry, PARTNER 1A and 1B, respective-ly). Presumably procedural outcomes continued to improve in this experience as the larger Italian CoreValve registry reported a lower mortality of 5.4%.

It must be remembered that the PARTNER 1 trials only exam-

ed TAVI in the highest risk 10% of patients (Figure 1). There are no randomized studies comparing TAVI and surgery for the other 90%, meaning that the high rates of TAVI in some countries are based on limited evidence. The ongoing PARTNER 2 and SURTAVI intermediate risk trials will only evaluate TAVI in the highest risk 25% of patients, meaning that extending the role of TAVI into the great bulk of lower risk patient will remain controversial for a long time.

Clearly TAVI is a moving target. The procedure continues to improve due to increasing experience, patient selection, and technical improvements.\textsuperscript{14} So too will clinical outcomes. Valve function and durability seem more than adequate for most patients currently considered to be at high risk with surgery. Whether clinical outcomes and durability will be adequate to compete with surgery in younger and healthier patients is unknown.

**Conflict of interests:** Edwards Lifesciences.

**References**