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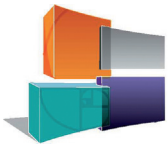

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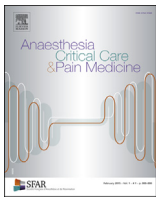

Editorial

Transcatheter Aortic Valve Replacement for symptomatic aortic stenosis: The default strategy?

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Transcatheter Aortic Valve Replacement (TAVR) has opened a new era in cardiovascular interventions. It has redefined the treatment of severe symptomatic aortic stenosis, starting with patients considered at high-risk for open surgery. Since then, three waves of randomised controlled trials have been published, making the research on TAVR one of the fastest growth regarding medical devices: 2011–2014 focused on high-risk patients, 2016–2017 on intermediate-risk patients, and finally 2019 on low-risk patients.

The benefit of TAVR is well established regardless of the expected risk of mortality, as defined by the Society of Thoracic Surgeons Predicted Risk of Mortality STS-PROM [1]. In high-risk patients (expected mortality superior to 15% within 30 days after surgery), TAVR resulted with a non-inferior one-year mortality compared to the open surgery approach [2,3], and could even lead in some instances to a better survival [4]. The cost-effectiveness of transfemoral TAVR has already been well reported in this population [5], as ICU and hospitalisation length-of-stay were reduced from one to two days each.

The following studies conducted in patients at lower risk of mortality evaluated the composite outcomes of long-term mortality and disabling stroke as the primary endpoint. In patients with intermediate surgical risk (expected mortality between 3 and 15% within 30 days after surgery) [6,7], the TAVR procedure demonstrated non-inferiority versus Surgical Aortic Valve Replacement (SAVR) and superiority in the prespecified femoral TAVR group.

Finally, two multicentre randomised clinical trials were conducted in low-risk patients defined as expected mortality < 3 to 4% within 30 days after surgery. The PARTNER 3 [8] and the Evolut Low Risk [9] trials were both funded by industrials, and used the two main transcatheter aortic valve (TAV) devices available: the balloon-expandable valve (PARTNER 3) and the self-expending valve (Evolut Low Risk). In the Evolut Low Risk trial, 1468 patients with mean STS-PROM of 1.9% were randomised. The 24-month estimated incidence of mortality and disabling stroke was 5.3% in the TAVR group versus 6.7% in the surgery group, meeting the prespecified criteria for non-inferiority. The PARTNER 3 trial included 1000 patients with mean STS-PROM of 1.9%. The composite primary outcome of mortality, stroke and re-hospitalisation at one year was significantly lower in the TAVR group than in the surgery group (8.5% versus 15.1%; hazard ratio 0.54; 95% CI, 0.37 to 0.79; $P = 0.001$ for superiority). To be noted, stroke and re-hospitalisation were the only two variables that were significantly lower in the TAVR group. Considering the short-term 30-day secondary endpoints, the TAVR procedure was superior to SAVR regarding incidence of disabling stroke, bleeding complications, acute kidney injury and atrial fibrillation. Compared to SAVR, hospital length-of-stay in the TAVR group was reduced in the balloon-expandable valve trial (-4.0 days compared to open surgery) but not in the self-expanding valve trial. This may be due to the higher incidence of cardiac conduction disorders with the latter valve. Indeed, the 30-day incidence of permanent pacemaker implantation in the TAVR group was 17.6% when using the self-expanding valve (compared to 6.1% in the open surgery group) and 6.5% (compared to 4% in the open surgery group) when using the balloon-expendable valve. Based on these results, how should we consider the benefit-risk ratio in patients with severe symptomatic aortic stenosis?

The efficacy and the safety of the TAVR strategy is well documented on the short and mid-term, but the long-term safety of TAVR in lower risk patients remains a pending issue. Valve durability is a potential challenge as all biological heart valves endure structural degeneration with time, and TAV might degenerate even faster than surgical aortic valves due to suboptimal implantation or constraint on the valve within the delivery catheter [10]. However, long-term follow-up registries do not seem to show any difference in terms of structural valve deterioration or bioprosthetic valve failure [11,12]. When treating lower-risk patients with TAVR, the age of the patient must be taken into account: the mean age of patients included in low-risk trials [8,9] was 73.6 years, compared to about 80.8 years in intermediate-risk trials [6,7] and 83.9 years in high-risk trials [2–4]. Indeed, patients with a life-expectancy exceeding 10 years may choose open-heart surgery at higher risk with a mechanical prosthetic valve, with long-term anticoagulation, instead of a lower-risk

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TAVR, which may need to be replaced after several years. A better understanding of the management of TAV degeneration is needed, given the exponential number of patients that could potentially require a second procedure with TAVR on younger patients. The outcomes of the "TAV-in-valve" procedure, meaning the completion of a TAVR in a surgical prosthetic valve, are accumulating, but only a small number of patients experienced a redo TAVR ("TAV-in-TAV" procedure), predominantly for paravalvular regurgitation during the first year after the index TAVR [13]. The safety of this strategy needs to be evaluated, given the potential risk of the second valve malposition or coronary arteries obstruction. The results of registries of patients who have undergone a TAVR will probably address this issue, as well as the other limitation of the recent studies on TAVR, i.e. the selection bias. The studies on low-risk patients mainly included men (about 65%), and excluded patients with bicuspid aortic valve stenosis. New-generation TAVs seem to have similar success rates and mortality outcome on both tricuspid and bicuspid valves [14,15], despite an increase in the 30-day risk of stroke among those with bicuspid aortic stenosis.

To conclude, TAVR plays a major role in the management of patients over 70 years of age, without associated cardiac conditions requiring open surgery (need for cardiac artery bypass graft surgery) or contraindication for TAVR (anatomical features). The benefit/risk ratio of TAVR for younger patients will have to be carefully weighed in the coming years.

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Disclosure of interest

The authors declare that they have no competing interest.

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