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Review Article

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Transcatheter Versus Surgical Aortic Valve Replacement in Intermediate-Risk Older Adults: A Review of the Evidence

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Abstract

Severe symptomatic aortic stenosis in older adults is treated by replacing the valve, and for patients whose predicted operative mortality is intermediate the choice between transcatheter implantation and surgery has been tested in two large randomised trials. This narrative review sets out what those trials, their longer follow-up and the related observational and pooled analyses show. Both trials found the transcatheter approach non-inferior to surgery for death or disabling stroke at two years, and the five-year report of the larger trial found no significant difference overall. The two procedures fail in different ways: surgery brings more bleeding, acute kidney injury and new atrial fibrillation, whereas transcatheter implantation brings more vascular injury, paravalvular regurgitation and, with self-expanding devices, more permanent pacemakers. Access route matters, and the case for the transcatheter approach is strongest when the femoral route is available. The review also considers what the risk scores do not measure, notably frailty, and what the trials did not study, including bicuspid valves and durability beyond the first few years. Current guidelines have moved from risk category towards age, anatomy and life expectancy, and the reasons for that shift are explained.

Keywords: Aortic stenosis, Transcatheter aortic valve replacement, Surgical aortic valve replacement, Intermediate surgical risk, Older adults, Heart Team

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1. Introduction

Calcific aortic stenosis is a disease of ageing. Its prevalence rises steeply in the later decades of life (Nkomo et al., 2006), and once angina, syncope or heart failure appears the outlook without valve replacement is poor, as Ross and Braunwald (1968) described in an account that still frames clinical thinking. No drug slows the calcification of the leaflets. The treatment is mechanical relief of the obstruction, and for half a century that meant surgical aortic valve replacement through a sternotomy on cardiopulmonary bypass.

The first transcatheter implantation in a human, reported by Cribier et al. (2002), opened another route. The technique was tested first in the patients surgery could not help. In people judged unsuitable

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for operation it reduced mortality compared with medical care that included balloon valvuloplasty (Leon *et al.*, 2010). In high-risk surgical candidates it gave survival similar to surgery with a balloon-expandable valve (Smith *et al.*, 2011; Kodali *et al.*, 2012) and compared favourably with surgery with a self-expanding one (Adams *et al.*, 2014). Each success prompted the same question about the next group down the risk scale.

This review concerns that next group: older adults at intermediate surgical risk. They are numerous, they are usually in their late seventies or eighties, and for them a conventional operation is a reasonable undertaking with a real but not prohibitive hazard. The review asks what the published evidence says about choosing between the two procedures for such patients, where that evidence is firm, and where it runs out.

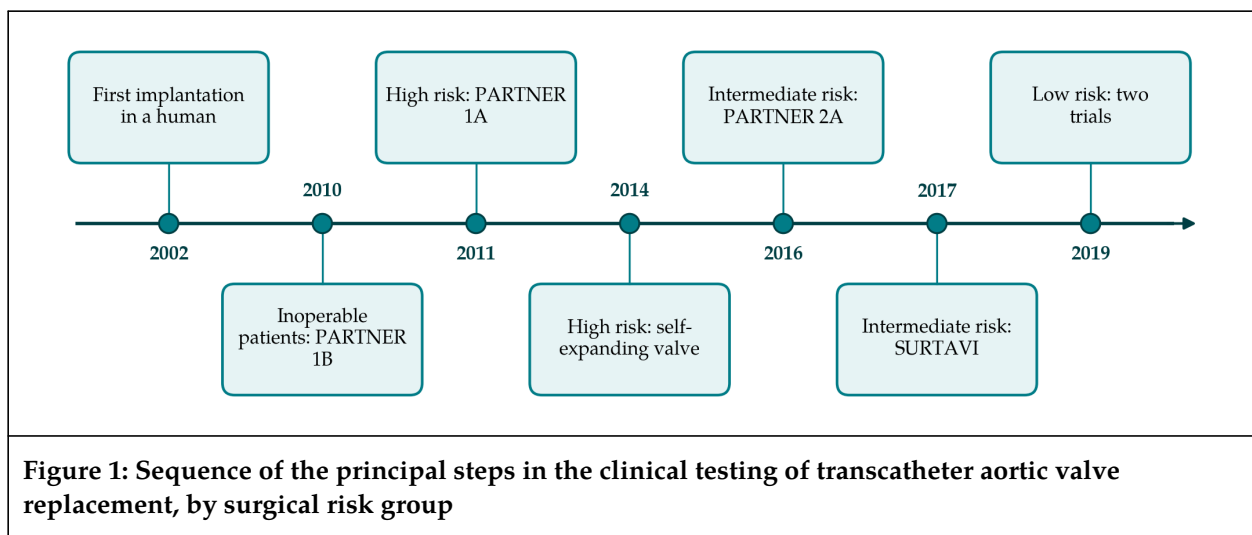
2. Scope and Approach

This is a narrative review of the published literature. It rests on the two randomised trials that enrolled intermediate-risk patients, their follow-up reports, one trial in a mostly lower-risk population that helps with interpretation, a pooled analysis of the randomised trials, and the American and European guidelines. No formal search protocol was applied and no new analysis is offered. Trial results are described in words; readers who need the exact estimates should consult the original reports.

The term intermediate risk needs a definition. By convention it refers to a predicted 30-day mortality of 4% to 8% on the Society of Thoracic Surgeons score, a model derived from a large surgical registry (O'Brien *et al.*, 2009). European practice has often used EuroSCORE II for the same purpose (Nashef *et al.*, 2012). In both trials a local team of cardiologists and surgeons could also assign a patient to the intermediate category on clinical grounds, so the populations were not defined by the score alone.

3. The Randomised Trials

Figure 1 places the two intermediate-risk trials in the sequence of randomised comparisons that carried the transcatheter procedure from inoperable patients to low-risk ones. Table 1 summarises their design and principal findings side by side.



3.1. PARTNER 2A

The PARTNER 2A trial assigned intermediate-risk patients with severe symptomatic aortic stenosis to a second-generation balloon-expandable valve or to surgery (Leon *et al.*, 2016). Patients were first assessed for femoral access. Roughly three quarters were suitable and formed a transfemoral cohort; the remainder were placed in a transthoracic cohort, in which the valve was delivered through the apex of the left ventricle or directly through the aorta. The primary end point was death from any cause or disabling stroke at two years, and the transcatheter approach met the criterion for non-inferiority. In the

transfemoral cohort the rate of the primary end point was lower with the transcatheter valve than with surgery; in the transthoracic cohort the two treatments gave similar results.

The secondary findings showed two different patterns of harm. Surgery was followed by more severe bleeding, more acute kidney injury and more new-onset atrial fibrillation, and by a longer stay in intensive care and in hospital. Transcatheter implantation gave larger valve areas on echocardiography but more major vascular complications and more paravalvular regurgitation. Regurgitation of moderate or greater degree was associated with higher later mortality, a finding already familiar from the high-risk trials (Kodali et al., 2012).

3.2. SURTAVI

SURTAVI tested a self-expanding valve against surgery in a population whose mean predicted risk lay towards the lower end of the intermediate range (Reardon et al., 2017). The primary end point was again death or disabling stroke, assessed at 24 months with a Bayesian analysis, and again the transcatheter approach was non-inferior. Surgery carried higher rates of acute kidney injury, atrial fibrillation and transfusion. The self-expanding valve carried higher rates of residual aortic regurgitation and a markedly higher rate of permanent pacemaker implantation, a consequence of the pressure the frame exerts on the conduction tissue beneath the valve.

Table 1: Design and principal findings of the two randomised trials in intermediate-risk patients		
Feature	PARTNER 2A	SURTAVI
Source	Leon et al., 2016	Reardon et al., 2017
Transcatheter device	Balloon-expandable, second generation	Self-expanding, two generations
Access	Transfemoral and transthoracic cohorts	Predominantly transfemoral
Primary end point	Death or disabling stroke at two years	Death or disabling stroke at 24 months
Main result	Non-inferior; favourable in transfemoral cohort	Non-inferior
More frequent after surgery	Severe bleeding, kidney injury, atrial fibrillation	Kidney injury, atrial fibrillation, transfusion
More frequent after transcatheter valve	Vascular injury, paravalvular regurgitation	Pacemaker implantation, residual regurgitation

3.3. Supporting comparisons

Two further sources help in reading these trials. A third-generation balloon-expandable valve with an external sealing skirt was studied in a single-arm intermediate-risk cohort and compared, by propensity score, with the surgical arm of PARTNER 2A; the composite of death, stroke and significant regurgitation at one year favoured the newer device (Thourani et al., 2016). The comparison is not randomised and should be weighed accordingly, but it suggests that the paravalvular leak seen in the trial was partly a property of the device generation. The NOTION trial, which enrolled patients aged 70 or over regardless of risk and so recruited mostly low-risk people, found no significant difference between a self-expanding valve and surgery in its composite end point at one year (Thyregod et al., 2015).

A meta-analysis that pooled the randomised trials available by 2016 reported lower all-cause mortality at two years with transcatheter implantation, an advantage confined to transfemoral procedures (Siontis et al., 2016). Pooling across risk groups and device generations has obvious limits, yet the consistency of the access-route effect across trials is one of the more robust observations in this literature.

4. Durability and Longer Follow-up

Two years is a short horizon for a prosthesis. The five-year report of PARTNER 2A found no significant difference between the groups in death or disabling stroke for the trial as a whole (Makkar et al., 2020).

Within the transthoracic cohort the outcome was worse after the transcatheter procedure than after surgery. Paravalvular regurgitation, repeat hospitalisation and aortic valve reintervention were all more frequent after transcatheter implantation. The five-year results of SURTAVI likewise showed similar rates of death or disabling stroke in the two arms ([Van Mieghem et al., 2022](#)).

These reports settle less than might be hoped. Surgical bioprostheses are known to degenerate mainly in their second decade, and five years of follow-up in a population with a mean age near 80 says little about how a transcatheter valve will behave in a patient who lives fifteen years. Imaging studies have added a further uncertainty. Computed tomography has shown reduced leaflet motion consistent with subclinical thrombosis on a proportion of bioprosthetic valves, both transcatheter and surgical ([Makkar et al., 2015](#)); its bearing on durability and on stroke has not been established. Comparison across studies has been helped by the standardised end point definitions of the Valve Academic Research Consortium ([Kappetein et al., 2012](#)).

5. What the Risk Scores Leave Out

The surgical scores were built to predict death after an operation and were calibrated on people who were actually operated on. They contain no measure of frailty, cognitive state or dependence, the features that most distinguish one eighty-year-old from another. In a prospective multicentre cohort of older adults undergoing either procedure, frailty measured with a short four-item instrument predicted death and disability at one year beyond what the conventional scores offered ([Afilalo et al., 2017](#)). A patient labelled intermediate by a score may therefore be robust or may be close to the point at which neither procedure restores independence.

Anatomy is also absent from the scores. A heavily calcified ascending aorta, previous chest irradiation or patent bypass grafts lying behind the sternum raise the hazard of surgery without changing the calculated figure. Small or tortuous iliofemoral arteries, a low coronary origin, bulky calcium in the outflow tract or a very large annulus do the same for the transcatheter route. For these reasons both major guidelines give their strongest grade of recommendation to assessment by a multidisciplinary Heart Team, and not to any threshold on a score ([Otto et al., 2021](#); [Vahanian et al., 2022](#)).

6. From Risk Category to Age and Life Expectancy

While the intermediate-risk trials were maturing, two trials in low-risk patients reported. A balloon-expandable valve gave a lower rate of death, stroke or rehospitalisation at one year than surgery ([Mack et al., 2019](#)), and a self-expanding valve was non-inferior to surgery for death or disabling stroke at two years ([Popma et al., 2019](#)). Once the procedure had performed acceptably at every level of surgical risk, risk category lost much of its value as the organising principle of the decision.

The guidelines reflect this. The American guideline frames the choice chiefly by age and expected survival: surgery is favoured in patients under 65, transfemoral implantation in those over 80, and either is considered reasonable between those ages after shared decision-making ([Otto et al., 2021](#)). The European guideline recommends surgery for younger patients at low risk and transcatheter implantation for those aged 75 or over, or at high risk, with individual assessment for the rest ([Vahanian et al., 2022](#)). The difference between the two documents is itself informative. It shows that the evidence supports a range of reasonable thresholds and does not fix one.

For the intermediate-risk older adult the practical reading is as follows. If the femoral route is suitable and the anatomy is favourable, transcatheter implantation offers an outcome at least as good as surgery over five years, with a quicker recovery and fewer of the complications that most trouble elderly patients after an operation. If femoral access is not possible, the trial evidence gives no reason to prefer the transcatheter approach, and surgery remains the better-supported choice. If other cardiac surgery is needed at the same time, such as multivessel coronary grafting or repair of another valve, an operation addresses both.

7. Gaps in the Evidence

Several groups of patients common in practice were excluded from the trials. Both intermediate-risk trials excluded congenitally bicuspid valves, which are over-represented among the younger old. Patients with severe renal impairment, with very poor ventricular function or with predominant regurgitation were also left out. Results in these groups come from registries, with the selection effects that registries carry.

Three questions about the longer term remain open. One is durability beyond ten years, which determines whether a patient treated at 70 will need a second valve and by what means. A second is lifetime management: whether coronary arteries can be reached for angiography and intervention after a transcatheter valve, and whether a second valve can be placed safely inside the first. A third is the consequence of a permanent pacemaker and of mild paravalvular leak over many years. None of these can be answered from the trials reviewed here, and each bears more heavily on the fit 72-year-old than on the frail 86-year-old.

Finally, the outcomes that matter most to older people are thinly reported. Death and disabling stroke were sensible primary end points for regulatory trials. Return to independent living, cognitive change and time spent at home are harder to measure and were secondary or absent. Future trials in elderly populations would be more useful to patients and to Heart Teams if they were built around such measures.

8. Conclusion

Two randomised trials, with five years of follow-up, show that transcatheter aortic valve replacement is a sound alternative to surgery in intermediate-risk older adults, and that its advantage depends on transfemoral access. The procedures differ less in survival than in the kind of complication they cause. Risk scores sort patients only roughly, and frailty, anatomy and expected length of life should carry more weight in the decision. What is not yet known, above all how the valves last, matters least to the oldest patients and most to the youngest, which is why guidelines now set their thresholds by age.

Conflict of interest

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