EDITORIAL

TAVI – assessing the need for circulatory support

Christopher J Allen, Alison M Duncan, Neil E Moat, Alistair C Lindsay

Authors

Christopher J Allen
CT2 Core Medical Trainee

Alison M Duncan
Associate Specialist Cardiology

Neil E Moat
Head of TAVI Programme

Alistair C Lindsay
Interventional Cardiologist

Royal Brompton Hospital, Sydney Street, London SW3 6NP

Correspondence to:
Dr A Lindsay
(a.lindsay@rbht.nhs.uk)

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Transcatheter aortic valve implantation (TAVI) for severe aortic stenosis (AS) has expanded exponentially since it was first described 12 years ago, with around 100,000 procedures performed worldwide.[1,2] Randomised controlled trials have established TAVI as the treatment of choice for severe AS in patients of prohibitive surgical risk and as a viable alternative to surgical aortic valve replacement (SAVR) in high-risk candidates.[3–5] The feasibility and safety of TAVI is further supported by a large body of 'real-world' data from multi-centre registries with 93% 30-day and 79% one-year survival in the UK.[6] Moreover, with growing operator experience and evolving valve technology, TAVI continues to expand beyond those populations originally studied, to include those with severe left ventricular dysfunction and those with failing surgical homografts (so called 'valve-in-valve' TAVI), for example.[7,8]

Detailed preoperative work-up and careful patient selection with input from multi-disciplinary 'heart teams' (cardiac surgeons, interventional cardiologists, anaesthetists, nursing staff) are integral to good practice and to minimising the risk of what remains a complex and often challenging procedure. Serious complications (e.g. severe aortic regurgitation, major bleeding, device embolisation, coronary occlusion, and aortic dissection) are uncommon (<5%), but may precipitate sudden haemodynamic collapse necessitating cardiopulmonary bypass (CPB) or other mechanical support. Current guidelines, therefore, mandate 'full haemodynamic capability' during TAVI;[9] data on how these translate to clinical practice and the precise impact of such provisions on outcomes remain relatively limited.

In a single-centre series, 12 (4%) of 313 patients undergoing TAVI with Sapien® valves (Edwards Lifesciences) required emergency CPB following complications resulting in haemodynamic collapse.[10] A disproportionate number (9, 75%) were via a transapical approach. In three patients a period of resuscitation with CPB was sufficient for recovery, whilst nine required complication-specific procedures (e.g. valve-in-valve TAVI, conversion to open procedure and SAVR). Seven patients required additional circulatory support – five via intra-aortic balloon pump (IABP), and two via veno-arterial extracorporeal membrane oxygenation [VA-ECMO]). Thirty-day mortality was 16% (two patients) with only 45% survival at 12 months; far lower than in TAVI patients not requiring emergency CPB. Of note, all procedures were performed in a hybrid operating suite with cardiac surgeons, an anaesthetist, a perfusionist and a prepared CPB machine on standby. The authors' attribute 'expeditious' achievement of CPB to these facilities and preoperative 'rescue-planning' including the routine discussion of bypass cannulation strategy.

Elective CPB in high-risk cases

Elective CPB was trialled in 35 TAVI patients (32 with Sapien® valves, three with CoreValve® [Medtronic]) of very high risk (logistic EuroScore 59%, STS 35%). The procedure was carried out principally because rapid ventricular pacing in patients with known poor left ventricular function can lead to an irretrievable decline in cardiac output.[11] Overall technical success (94%) and periprocedural complications (e.g. postprocedure permanent pacemaker) were comparable to the standard TAVI cohort, suggesting planned CPB may be a feasible adjunct in high-risk cases that may otherwise have been declined TAVI. In another centre, 18 of 256 patients underwent TAVI with VA-ECMO support as either a prophylactic (initiated preprocedure due to poor left ventricular function, n=9) or emergency measure (secondary to complications including ventricular perforation and refractory cardiogenic shock, n=9).[12] Whilst the VA-ECMO cohort were significantly higher risk (median logistic EuroScore 26% *vs.* 15%), outcomes in the prophylactic group remained comparable with conventional TAVI patients, whereas requirement for emergency VA-ECMO was associated with

significantly lower procedural success (44% *vs.* 97%) and higher 30-day mortality (44% *vs.* 7%).

From the available data it would appear that the ability to provide surgical mechanical support, such as CPB or VA-ECMO, is important for any centre providing TAVI. To this end, in this issue (see pages 113–14), Spiro and colleagues highlight some interesting variations in CPB and surgical provision amongst the 33 UK TAVI centres.[13] The authors' survey revealed CPB equipment was immediately available in the catheter lab in 22 (67%) centres, with only 20 centres (52%) routinely employing a full surgical team and holding a cardiac theatre in reserve. The chief driver of heterogeneity was the valve system deployed, since 17/18 (94%) were centres exclusively using Sapien® valves and routinely had CPB equipment in the catheter lab – 16/18 (89%) with full surgical provision, compared to 3/10 (30%) centres using CoreValve® with CPB equipment and 2/10 (20%) with surgical back-up (p=0.0003 and p=0.008, respectively).

Challenges ahead

Whilst the study was not designed to assess the impact of these variations on outcomes, the results clearly reflect a key challenge for future UK TAVI practice. Where should TAVI be performed and with what facilities? Given the potential for uncommon yet serious complications, it can be reasonably argued that the safest environment is a hybrid theatre with immediate full surgical provision. The economic realities of UK healthcare mean this scenario is currently far from commonplace, whilst the resource implications of maintaining a free, fully-staffed cardiothoracic theatre routinely must not be underestimated. Moreover, the low event-rate of serious complications and inconsistencies in reporting in what are mainly observational data at present preclude meaningful conclusions on the precise influence of such preparations on outcomes.[14]

Evolution in valve design and delivery systems (e.g. smaller profile devices, more flexibility, repositionability) may in the near future reduce the risk of TAVI further, but cardiologists and cardiothoracic surgeons will simultaneously be asked to perform TAVI on increasingly complex, high-risk patients. Clearly, the minimisation of serious complications remains a principal aim of this rapidly evolving technique, thus as predictors of higher risk patients continue to emerge,[15] and with the potential benefits of 'prophylactic' mechanical support described above, randomised studies into the influence of sophisticated stratification of CPB and surgical provision on outcomes are likely to be needed ●

Conflict of interest

None declared.

Editors' note

See also the article by Jon Spiro *et al.* on pages 113–14 of this issue.

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