

## Editorial

## Transcatheter aortic valve implantation: Coming of age



## Implantación transcatóter de la válvula aórtica: la mayoría de edad

Michael Wayne Art Chu\*, Katie Lynn Losenno

Division of Cardiac Surgery, Department of Surgery, Western University, Lawson Health Research Institute, London, Ontario, Canada

Transcatheter aortic valve implantation (TAVI) has achieved wide spread adoption in many centres worldwide for the treatment of non-operable and high-risk patients with severe aortic stenosis. Sabate et al. present results from a national registry database representing 80% of all TAVI cases performed in Spain since January 2010, including both available prostheses (Medtronic CoreValve and Edwards SAPIEN) and all vascular access routes utilized.<sup>1</sup> This report provides valuable insight into the overall profile of TAVI and treatment of high-risk aortic stenosis patients within a specific country. Many other published registries provide fragmented data with outcomes based upon a specific device, access route or selected centres, introducing biases and limiting generalizability of the data. These results confirm that technical proficiency has been broadly achieved in Spanish TAVI centres with good procedural success rates and excellent perioperative outcomes. Their early and 1-year results are similar to other published registry data from Canada, United Kingdom, France, Germany, Italy, Belgium and Australia/New Zealand,<sup>2</sup> which is reassuring for the implanting TAVI teams as well as their patients.

The authors and all participating TAVI teams in Spain should be congratulated on a number of different levels. This report represents the successful creation of a central National TAVI Committee to prospectively collect high-quality patient data on TAVI procedures from most of the implanting centres in Spain. This is an impressive feat, particularly in the highly politicized climate of TAVI, that demonstrates great collaboration between cardiovascular centres and amongst cardiology and cardiac surgery teams. These partnerships are critical for achieving optimal patient outcomes and for the future of transcatheter valve therapies. This Spanish central data repository will serve as an invaluable resource not only to monitor trends in TAVI procedures and patient outcomes but will become a powerful vehicle to develop new science and perform multicenter, randomized trials necessary to advance the field of TAVI. Reporting TAVI patient outcomes from a central, national registry helps to reduce the impact of the usual biases inherent to observational case studies, so commonly present within the TAVI literature. Consideration could be made to expand the database to include all patients with severe aortic stenosis, in particular, medical therapy alone and conventional surgical aortic valve replacement outcomes, so to provide more comprehensive data on the outcomes of the entire disease process itself. If the remaining Spanish TAVI centres could be convinced to participate in this initiative as well, it could become a very powerful resource worldwide for TAVI research.

Although this report highlights the successful adoption of TAVI in Spain, it also reinforces the persistent and worrisome complications that occur following TAVI despite improved operator experience. In-hospital mortality has certainly improved over the last decade; however, mortality rates appear to have reached a plateau at about 5% risk in even the most experienced hands. Treatment of extreme risk patients (STS score  $\geq 15\%$ ) may be futile, as patient outcomes have been poor in this population. More importantly, ongoing 1-, 2- and 3-year mortality rates remain significant despite successful TAVI implantation, suggesting a persistent late mortality risk, likely related to patient co-morbidities; however, these could also be related to problems with late stroke and paravalvular leak.

Stroke remains a major and devastating complication associated with TAVI. While some smaller, observational studies report 30-day stroke rates as low as 1.7%, larger, randomized clinical trials have suggested stroke rates of 6.7% at 30-days and 10.6% at 1 year.<sup>3</sup> Although the mechanism of neurologic injury during TAVI is multifactorial, manipulation of calcified aortic valves and atheromatous aortas along with peri-procedural embolic events are likely culprits in many patients. Recognition of these embolic events has led to the development of “embolic deflection devices”. These devices are placed in the aortic arch and are intended to prevent embolic debris from entering cerebral circulation; however, many of these devices remain experimental and are largely unproven.<sup>4</sup> Careful guidewire manipulation and minimizing aortic trauma may help to reduce stroke risk.

Paravalvular leak and aortic insufficiency remain an underappreciated but significant complication after TAVI. Some degree of paravalvular leak may occur in up to 75% of patients after TAVI and significant paravalvular leak in 10–20% of patients. This report by Sabate et al. confirms the findings of others that moderate or severe residual aortic insufficiency after TAVI is associated with significantly elevated early and late mortality risks.<sup>6,7</sup> In fact, even mild paravalvular leak is associated with a significant risk of late mortality.<sup>3,4</sup> Paravalvular leak is an important complication after TAVI and is associated with at least a 2-fold increase in early and late mortality risk.<sup>7</sup> It is best to be avoided with appropriate valve sizing and optimal valve positioning; however, when it occurs, repeat balloon valvuloplasty, valve in valve and surgical aortic valve replacement should be considered.

Vascular access complications remain the Achilles heel of the transfemoral arterial approach for TAVI. Major vascular injury such as thoracic aortic dissection, access site or access-related vascular injury, end-organ damage, distal embolization from a vascular source or left ventricular perforation were reported in up 11% and 16.9% of patients in the PARTNER trial group A and group B, respectively.<sup>3,5</sup> Minor vascular complications were even more frequent occurring in approximately one-third of all patients at 1-year after TAVI.<sup>3</sup> The persistently high incidence of vascular

\* Corresponding author at: B6-106 University Hospital, 339 Windermere Road, PO Box 5339, London, Ontario, Canada N6A 5A5. Tel.: +1 519 663 3593; fax: +1 519 663 3276.

E-mail address: michael.chu@lhsc.on.ca (M.W.A. Chu).

injuries highlights the necessity for appropriate patient selection and utilization of alternative access routes such as transapical, transsubclavian and direct aortic approaches in patients with inadequate iliofemoral diameters. Newer generation, low-profile valves may also play a role in reducing vascular injuries by allowing for a decrease in sheath diameter and safer deployment of the prosthesis.

Transcatheter aortic valve implantation has revolutionized the treatment of high risk patients with aortic stenosis in Spain. These patients have been afforded significant relief of symptoms and greatly improved survival because of the excellent care delivered by the collaborative cardiology and cardiac surgery TAVI teams. Complications after TAVI persist and must be the focus of future investigations to improve overall patient outcomes.

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#### Conflicts of interest

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