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The Current State and Future Directions of Transcatheter Aortic Valve Implantation

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EDITORIAL

Currently, surgical aortic valve replacement (SAVR) remains the standard of care for most patients with symptomatic severe aortic stenosis (AS). However, transcatheter aortic valve implantation (TAVI) has emerged as an alternative option for patients with symptomatic AS who have a prohibitive risk profile for SAVR. This rapidly expanding field is a dynamic one, largely due to overwhelming developments in transcatheter valves, delivery systems, and access routes. Though groundbreaking and promising, the novel approach is not without limitations. Current risk-scoring systems have proven inadequate, and an absence of standard guidelines has complicated the selection of an appropriate valve and access route to meet a patient's individual needs [Gurvitch 2011; Neragi-Miandoab 2012; Neragi-Miandoab 2013a]. Imaging studies such as CT scanning and echocardiography are useful tools to decipher annular shape, anatomy of coronary arteries, and severity of calcification. These factors may help to individualize the approach and valve type required. The indications for TAVI, currently guided by retrospective evaluation of limited clinical data, require significant modification and revision of the risk-scoring system for TAVI candidates. Furthermore, in order to expand indications and to make TAVI available to intermediate- and low-risk patients, prospective randomized trials must be undertaken. The advent of new devices and a broadened understanding will reduce TAVI-related adverse events and promote positive outcomes. It is not to be overlooked that some perioperative risks are more salient in TAVI than in SAVR. The recently developed Valve Academic Research Consortium criteria, while crucial to the field, may need to be simplified for use in clinical practice to make documentation of postoperative complications feasible.

A reoperative SAVR to replace a degenerated biologic prosthetic valve carries a high risk in elderly patients with complicating comorbidities [Gotzmann 2010; Eggebrecht 2011; Neragi-Miandoab 2013b]. TAVI, through the valve-in-valve technique, presents a promising option in the management of patients with degenerated bioprosthetic valves [Eggebrecht 2011]. Although the hemodynamic improvement following transcatheter valve-in-valve procedures is acceptable [Eggebrecht 2011; Linke 2012], this approach has some limitations. Hemodynamics of valve-in-valve intervention using a small bioprosthetic valve (19 and 21 mm) are less favorable with the transcatheter approach compared to the surgical approach [Azadani 2010]. A native stenosed aortic valve preserves some flexibility and allows expansion of the prosthesis; however, a calcified and rigid bioprosthesis may prevent full expansion of a new and oversized prosthetic valve within the old valve, disrupting leaflet function. Therefore, an oversized transcatheter valve is not recommended for the valve-in-valve approach due to the risk of central aortic insufficiency. Aortic root anatomy, coronary ostial position, and the specifics of the bioprosthetic valve type (particularly valve height) need to be individualized to each specific case [Gurvitch 2011].

Considering the high cost of TAVI, some authors have raised the issue of the cost-effectiveness of TAVI and the patient's quality of life after this procedure [Hartman 2008; Neyt 2012; Van Brabandt 2012]. In the targeted population of patients with multiple coexisting conditions, limited life expectancy, and disproportionate health care expenditures [Hartman 2008], a careful consideration of cost-benefit analysis of TAVI is suggested. This is especially crucial in an era with an increasingly aging population and ongoing health care reforms aimed at reducing expenses in North America and Europe. Further, the marketing approval for a high-risk

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device should be based on specific indications [Hulstaert 2012; Neyt 2012]. However, those indications should be based on clinical studies and guided by physicians rather than authorities that grant approval for the devices. The fast-track approval of medical devices by Committee Europe (CE) has been under criticism in recent years, and some European scientists endorse stricter regulations, like those enforced by the Food and Drug Administration (FDA) in the United States [Van Brabandt 2012]. Van Brabandt et al. [Van Brabandt 2012] make a valid point on the disparate ease of medical device approval and marketing in Europe. Gaining approval for medical device use and marketing in Europe (CE mark) is relatively simple, although on the other hand, the strict FDA regulations have delayed the introduction of innovative techniques into United States hospitals. The long process of obtaining approval from the FDA ultimately antagonizes innovation in the United States and, possibly, compromises patient care. While some concerns regarding the introduction of TAVI [Van Brabandt 2012] and the need for refinement and improvement of its technology are valid, interpretation of inconsistencies in clinical trials and shortcomings are often misguided and used to inappropriately reject the potential of new technology. The inconsistencies in clinical trials need to be discussed independently of the product under investigation. The introduction of laparoscopic cholecystectomy and an endovascular approach for the management of abdominal and thoracic aortic pathology was subject to the same concerns and rejections decades ago.

While bearing in mind the basic medical principle of respecting human life—primum non nocere—innovation remains one of the most crucial aspects driving our field. New technologies must be granted a fair chance of introduction to all markets as soon as safety concerns are addressed. Currently, a number of next-generation transcatheter aortic valves are under pivotal clinical trials in Europe and the United States. Each of the valves under development offers a potentially significant innovation that could simplify TAVI and improve clinical outcomes. Future areas of innovation should include technologies specifically designed for treatment of bicuspid aortic valve stenosis, transcatheter valve implantation for treatment of aortic regurgitation, and valve-in-valve techniques. Next-generation transcatheter aortic valves will have to address remaining TAVI-specific drawbacks, such as periprosthetic aortic regurgitation and conduction disturbance, to further reduce the rate of complications.

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