Implications of Contemporary Clinical Trials Series
The Placement of Aortic Transcatheter Valve Trial (PARTNER)

This latest addition to Implications of Contemporary Clinical Trials provides readers with a broad range of perspectives on a dramatic addition to the cardiologist’s therapeutic armamentarium: transcatheter aortic valve replacement (sometimes referred to as transcatheter aortic valve implantation). This new treatment for hemodynamically severe, symptomatic aortic stenosis represents a triumph of modern-day design of a new device and uses creative clinical design methodology. The discussions in this collection of articles cover the development of the transcatheter aortic valve replacement methodology and the pivotal Placement of Aortic Transcatheter Valve Trial (PARTNER) that evaluates its impact; implications from the interventional, surgical, and general cardiology perspectives; and importantly, a critique of the health economic implications of introducing a dramatically effective but expensive new therapy.

The timing of the publication of this collection of articles is noteworthy because the Centers for Medicare and Medicaid Services has just announced a National Coverage Decision with evidence development indicating that they have approved transcatheter aortic valve replacement (transcatheter aortic valve implantation) in patients with severe aortic stenosis.1 The 5 conditions that must be met are the following: (1) The procedure must use a device approved by the Food and Drug Administration; (2) 2 cardiac surgeons must have reviewed the patient’s candidacy for surgery; (3) a multidisciplinary heart team must be involved in the care of the patient; (4) interventional cardiologists and cardiac surgeons must be jointly involved in the technical aspects of the procedure; and (5) the hospital in which the procedure is performed must be participating in a prospective, national, audited registry.

As a clinical cardiology community, we can be proud of the development of this new treatment option for our patients. This set of articles in Circulation reminds us that we must also recognize our responsibility to use the new treatment appropriately and to participate in the development of an enlarging database from which the decisions about the next steps for transcatheter aortic valve replacement (transcatheter aortic valve implantation) will be derived.

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Reference
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_Circulation_. 2012;125:3054
doi: 10.1161/CIRCULATIONAHA.112.121251
_Circulation_ is published by the American Heart Association, 7272 Greenville Avenue, Dallas, TX 75231
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Print ISSN: 0009-7322. Online ISSN: 1524-4539

The online version of this article, along with updated information and services, is located on the World Wide Web at:
http://circ.ahajournals.org/content/125/25/3054

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