

Transcatheter Aortic Valve Implantation Shows Promise for Patients Too Sick for Conventional Surgery

University Of Pennsylvania

Just released data from a clinical trial shows promise for a new minimally invasive treatment option for patients with severe aortic stenosis who are too sick for traditional forms of open-heart surgery. As compared to standard medical therapy, the new procedure, transcatheter aortic valve implantation (TAVI), significantly reduced mortality rates in patients who received the new valve.

- [Click for information if you or a loved one would like to know more about the experimental treatment described on this page, including answers to the following questions:](#) [1]
 - [What is transcatheter aortic valve implantation?](#) [1]
 - [What is aortic stenosis?](#) [1]
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The [Hospital of the University of Pennsylvania](#) [5] (HUP) is a site for the Placement of Aortic Transcatheter Valves (PARTNER) Trial evaluating TAVI and [Joseph E. Bavaria, MD](#) [6], vice chief, Division of Cardiovascular Surgery and [Howard C. Herrmann, MD](#) [7], director, Cardiac Catheterization at HUP, are co-authors of a paper highlighting the results in the September 23, 2010 issue of the *New England Journal of Medicine*.

“Aortic stenosis is a common medical problem for patients over the age of 65 and the number of patients with this condition continues to climb as the U.S. population ages,” says Joseph E. Bavaria, MD. “Approximately 30 percent of patients with severe aortic stenosis are not candidates for traditional open heart surgery, due to others coexisting factors such as advanced age, left ventricular dysfunction, and other cardiovascular comorbidities.”

Currently, for patients at high surgical risk, the only therapy available is medical management of the condition. Even with medical management, patients generally have a poor prognosis if they cannot undergo surgery.

“The results from this arm of the clinical trial show that TAVI represents a life-saving

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therapeutic alternative for patients who are not able to undergo traditional surgery," said Howard C. Herrmann, MD. "The device used in this trial is not yet FDA approved, but the results are so promising that this therapy will likely open a new frontier in treating aortic stenosis."

The PARTNER Trial is a randomized, controlled pivotal trial of a transcatheter aortic heart valve – a collapsible and balloon-expandable valve that can be introduced into the body via a catheter-based delivery system. The valve replaces a patient's diseased valve without traditional open-heart surgery and while the patient's heart continues to beat.

The main results from the PARTNER Trial in patients with severe aortic stenosis who were not suitable candidates for surgery show that TAVI was superior to standard medical therapy, markedly reducing the rate of death from any cause by 20 percent, the rate of death from cardiovascular causes, and the rate of repeat hospitalization. Results also showed that standard medical therapy did not alter the natural history of severe aortic stenosis. At the end of one year, the rate of death from any cause was just over 50 percent for patients who received medical management alone.

The authors of the research caution that further study is needed to assess the risk of stroke in patients who have a TAVI procedure. The latest data release is from one arm of the PARTNER Trial. The second arm of the study, which compares the TAVI procedure to traditional open-heart surgery in healthier patients, is ongoing at HUP.

Dr. Bavaria reports receiving grant support from Edwards Lifesciences, maker of the valve used in the PARTNER Trial. Dr. Herrmann reports no potential conflicts with Edwards Lifesciences.

[SOURCE](#) [8]

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Links:

[1] http://www.uphs.upenn.edu/news/News_Releases/2010/09/transcatheter-aortic-valve-implantation/patient-resources.html

[2] <http://penncardiology.org/heart/>

[3] <http://www.med.upenn.edu/>

[4] <http://pennhealth.com>

[5] <http://penncardiology.org/hup>

[6] <http://www.pennmedicine.org/Wagform/MainPage.aspx?config=provider&P=PP&ID=823>

[7] <http://www.pennmedicine.org/Wagform/MainPage.aspx?config=provider&P>

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[8] http://www.uphs.upenn.edu/news/News_Releases/2010/09/transcatheter-aortic-valve-implantation/