Transcatheter aortic valve implantation as good as traditional surgery for high risk, operable patients

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The valve used in TAVI surgery.

Just released data from a clinical trial shows continued promise for a new minimally invasive treatment option for patients with severe aortic stenosis. New research presented at the 2011 American College of Cardiology (ACC) Scientific Sessions from the first arm, Cohort A, of the Placement of Aortic Transcatheter Valves (PARTNER) Trial shows that transcatheter aortic valve implantation (TAVI) is as good as traditional open heart surgery for high-risk, but operable patients. The Hospital of the University of Pennsylvania (HUP) is a participating site for the trial.

Speaking at the meeting as part of the panel presenting the data, Howard C. Herrmann, MD, director of the Interventional Cardiology and Cardiac

Catheterization Laboratories at Penn, said “The results are a win-win for patients. Surgery was better than expected and TAVI was even better at 30 days and as good as surgery at one year. High risk patients with this common life threatening disease will likely soon have a less invasive alternative to open heart surgery. I anticipate that the results of TAVI will only get better with experience and further improvements in the technology.”

Cohort A compared outcomes after treatment with either the TAVI procedure or traditional open-heart surgery in 699 high-risk, operable patients. The study is a "non-inferiority" trial designed to evaluate whether patient outcomes after transcatheter aortic valve replacement are comparable to surgical outcomes in these patients.

Researchers at the meeting cautioned that although the study met its primary endpoint of demonstrating non-inferiority to traditional surgery, major strokes and other vascular complications were higher in the TAVI-treated patients, both at 30 days and one year. By contrast, major bleeding was more than twice as common in the surgical group.

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 trial is studying the valve in both operable (Cohort A) and inoperable (Cohort B) patients with severe aortic stenosis.

Previous results from the trial indicated that this therapeutic option was viable for patients too sick to undergo traditional open-heart surgery (Cohort B). As compared to standard medical therapy, the new procedure, transcatheter aortic valve implantation significantly reduced

mortality rates in the patients who received the new valve.

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