Surgeons caution against overenthusiasm for TAVI in light of PARTNER A stroke data

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AATS **Philadelphia, PA** – The neurological injury data from the PARTNER cohort A trial of transcatheter aortic-valve intervention (TAVI) underscore the importance of the collaboration between surgeons and interventionalists when making decisions on how to treat patients in need of a new aortic valve, surgeons here at the American Association of Thoracic Surgery (AATS) 2011 Annual Meeting agreed.

Dr Craig Miller

As reported by heartwire, **Dr Craig Miller** (Stanford University, CA) presented new details on the neurological-event data from PARTNER cohort A, which included high-risk patients eligible for either surgery or TAVI. The data showed that the risk of neurological adverse events (transient ischemic attack [TIA] and stroke) was slightly higher with TAVI than surgery in the "as-treated" patients, especially in the patients who underwent transapical TAVI because their vessels were too small to accommodate a transfemoral implant, usually because they were obstructed with arteriosclerosis. Rates of major stroke, however, were not statistically different between the two groups in the as-treated analysis.

Because of the added neurological risk, Miller believes TAVI should not replace surgery for most patients who can withstand surgery. So he is dismayed that it has grown so rapidly in some European countries where TAVI devices are commercially available, even though the durability of these devices has not been proven. "This is not going to be cost-effective, and civilization cannot afford this if they do not last a good amount of time, and a good amount of time would mean something different to a 95-year-old who is inoperable and to somebody under 70 with a very low surgical risk who should have 10- to 20-year life expectancy. So we have to look at valve durability," he said.

"There are many [inoperable patients like] the people in PARTNER cohort B, who gained 1.9 quality-adjusted life-years, and it only cost $55K per QALY to achieve that. So for the inoperable cohort, it is cost-effective and actually provides meaningful rehabilitation, but the jury is out for the younger patients," he said. "But the cost economics of the not-so-sick operable patients is going to be different; they're still beaucoup sick and old in PARTNER A, but to take this down to younger, healthier patients is a huge question mark in my mind and in the **FDA**'s mind, because we already have the gold standard of low-risk, durable, surgical [aortic-valve replacement]," Miller said.

Surgeon/interventionalist collaboration is critical

Miller thinks one reason that TAVI has become "a runaway train" in Europe is that in some countries there, interventionalists are able to decide to implant a transcatheter valve without consulting a surgeon or, in some cases, even having a surgeon on site. "The German **Federal Ministry of Health** didn't have the backbone to stand up and legislate appropriate use, so it's a free-for-all. But that would be wrong, especially since we don't have durability data," Miller said. Miller said he learned that about a quarter of aortic-valve replacements in 2010 in Germany were TAVI procedures, but **Dr John Mayer** (Children's Hospital Boston, MA) reported at the meeting that the figure is now around 40%.

Mayer and **Dr Grayson Wheatley III** (Arizona Heart Institute, Phoenix) echoed Miller's concerns about overenthusiasm for TAVI during a staged luncheon debate on whether or not expensive technologies like TAVI ought to be somehow rationed to control healthcare costs. Mayer took the position of defending rationing and Wheatley argued against it, but they both agreed that physicians and their professional societies ought to work to ensure appropriate use of TAVI.

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Wheatley said, "We're probably going to see something along the carotid-stent paradigm, where it's FDA approved, but [the **Centers for Medicare & Medicaid Services**] CMS has restricted [coverage] of an FDA-approved device, based on the data and economics, to the highest-risk patients. I see a lot of parallels there."

"The Medicare national coverage decision process is going to undoubtedly come into play," Mayer agreed. "That's one way to control it, and that's probably the biggest weapon in the arsenal." Mayer said that the CMS is already discussing a future Medicare coverage policy for TAVI with the **Society of Thoracic Surgeons** (STS).

"But the other way to control it is to take the combined cardiology/cardiothoracic surgery approach to be careful about how this gets rolled out," he said. The STS and the **American College of Cardiology** (ACC) are currently working on a joint position paper that will call for TAVI appropriateness guidelines based on the PARTNER results, Mayer pointed out. That paper will likely be published this summer. "That's an extremely important step, and I think the government will understand and accept a lot of the recommendations in there."

Meanwhile, the **Society for Cardiac Angiography and Interventions** (SCAI) will be contributing to the STS/ACC position paper

and is also developing an expert consensus document with representatives from the AATS, STS, and ACC that will outline training and facility standards for performing TAVI. That document will be published prior to the **TCT 2011** conference, according to SCAI.

"The difference between how this was rolled out in Europe and how the investigators in the PARTNER trial would like to roll it out in the United States is that a heart team with a surgeon and cardiologists—and not just the interventional cardiologists, but general cardiologists—make the decisions jointly. That is the model that we think should be imposed going forward," Mayer said. This collaboration will "be a way of us fulfilling our professional responsibility and making sure that this gets rolled out with high quality and will have the side benefit of keeping it from going nuts like it has in Europe."

While some may be better off undergoing surgery than transfemoral TAVI, there are also some patients whose risk of neurological injury is so high due to arteriosclerotic burden that they are probably not suitable for either surgery or TAVI, Miller said. "The only thing that's going to change that is more rigorous patient selection and just saying no," Miller told **heart*wire***. "That might not go over well in the US where everybody demands everything yesterday, [but] since these are patient-disease-related predictors, more rigorous patient selection is the only thing that will reduce the late hazard of neuro events [in patients with very high arteriosclerotic burden]."

What does PARTNER cohort A reveal about the cause of strokes?

STS president and PARTNER investigator **Dr Michael Mack** (Medical City Dallas Hospital, TX) told **heart*wire***, "There was an initial thought for the past few years that the transapical might be more neuroprotective than the transfemoral because you don't transverse the aortic arch with the device, and I think this puts to bed that that was not the case. In fact, the stroke rate was higher in the transapical than in transfemoral, but the presentation showed that it was clearly related to the patient substrate." The one-year stroke rate in the transfemoral-eligible surgery patients was 1.9%, while the one-year stroke rate for the same surgical procedure in transfemoral-ineligible patients was 9.7%, Mack pointed out. "That says they're different patients [with] a higher atherosclerotic burden."

> **[Collaboration will make] sure that [TAVI] gets rolled out with high quality and will have the side benefit of keeping it from going nuts like it has in Europe.**

Mack pointed out that the version of the **Sapien** valve (Edwards Lifesciences) tested in PARTNER was a first-generation device that did not have the nose cone that newer versions will have, "so you basically had this snowplow that could go across the aortic arch and scrape stuff off; smaller delivery devices with nose-cone protection may be expected to be of benefit," Mack said. However, previous studies with transcranial Doppler show that the majority of the emboli come from the valve during balloon valvuloplasty and deployment of the valve and not from the aortic arch. "[This is] why you don't see a benefit of the transapical here, because you're still blowing up that valve [inside the native valve]."

This explanation is consistent with the study's finding that, in the first few weeks following the procedure, a smaller valve opening area, which is usually a sign of high calcification around the opening, was associated with a higher risk of neurological events in the TAVI patients. Embolic-protection devices, such as Edwards's **Embrella**, may catch some of these emboli released during the valve deployment, Mack said, but clinical experience with these devices is very limited so far.

Better devices may stop a lot of the periprocedural events, but about half of the neurological events happened after the periprocedural period. In this period, the most important risk factor—other than undergoing TAVI instead of surgery or being transfemoral ineligible—was a stroke or TIA within the previous six to 12 months. Atrial fibrillation, which was predicted by some to possibly be a risk factor for strokes, was not associated with an increased risk of neurological events in the study. Dual antiplatelet therapy was recommended for all patients in the trial, but the trial could not track how compliant patients were with that therapy.

"We have absolutely no clue if these strokes were device related or not. We don't know if the device is thrombogenic, or if all that calcium left in the aorta hanging out eventually breaks out, or if it's a nidus for clot formation and that breaks off. We just don't have any insight on that," Mack said.

PARTNER was sponsored by Edwards Lifesciences. Miller has consulting arrangements with Medtronic CardioVascular, Abbott Vascular, and MitraClip. Mack consults for Edwards Lifesciences and Medtronic.

Related links

- PARTNER A: Stroke with TAVI speaks to arteriosclerotic burden, baseline risk
  [*Interventional/Surgery > Interventional/Surgery*; May 09, 2011]
- PARTNER cohort A: Transcatheter valves noninferior to surgery
  [*Interventional/Surgery > Interventional/Surgery*; Apr 03, 2011]
- Transcatheter aortic-valve implantation (TAVI): What does the future hold?
  [*Site Structure > Sections*; Jun 07, 2010]
- TAVI specialists expect surgical valves to survive, as more surgeons also do TAVI
  [*Interventional/Surgery > Interventional/Surgery*; Mar 02, 2011]
- Digesting PARTNER: Physicians react with superlatives to TAVI results

[*Interventional/Surgery > Interventional/Surgery*; Sep 23, 2010]

- Transcatheter valves slash deaths, hospitalizations vs standard care: PARTNER
[*Interventional/Surgery > Interventional/Surgery*; Sep 22, 2010]
- FRANCE: Transcatheter-valve registry permits "observation" of CoreValve, Sapien differences
[*Interventional/Surgery > Interventional/Surgery*; Nov 15, 2009]