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TAVI to treat surgical valve failure shows potential, with caveats

MAY 15, 2012 Shelley Wood

EuroPCR

Paris, France – The largest series to date looking at transcatheter aortic-valve implantation (TAVI) to treat the failure of a surgically implanted prosthetic has found high rates of survival at one year, but enough in the way of safety signals that investigators are cautioning against widespread use of the practice.

Dr Danny Dvir

"The valve-in-valve procedure, although feasible, is technically demanding, includes several safety concerns, and should probably be reserved for highly experienced centers," **Dr Danny Dvir** (Rabin Medical Center, Israel) said during the late-breaking clinical-trial sessions here at EuroPCR 2012. That said, the procedure in most patients is "clinically effective" and at least out to one year, patient survival is equivalent to—if not better than—that seen in other TAVI cohorts, where patients are undergoing native valve replacement.

As Dvir explained here, bioprosthetic surgical valves tend to fail 10 to 15 years after the initial implantation, and reoperations are often in high-risk patients who are typically elderly, with multiple comorbidities. Indeed, in his series, mean EuroSCORE was 38 and mean STS score was 12.

"These patients were sick," Dvir said simply.

Dvir and colleagues' global valve-in-valve registry combined data on 416 patients treated at 54 centers in Europe, North America, Australia, New Zealand, and the Middle East. The cause of valve failure was surgical valve stenosis in 168 patients, valve regurgitation in 125 patients, and a combination of the two in 123 patients.

Both the **CoreValve** (Medtronic) and **Sapien** (Edwards Lifesciences) were used to treat the failed surgical valves, with no differences in terms of the underlying cause of valve failure between the two types of TAVI devices.

Early and one-year results

At 30 days, all-cause and cardiac survival were highest among patients whose underlying cause of valve failure was regurgitation, followed by patients with a combination of regurgitation and stenosis, and lowest among patients who'd been referred for valve-in-valve treatment due to stenotic surgical valves.

At one year, roughly 85% of patients whose initial valve failure was due to regurgitation were still alive. That proportion fell to approximately 70% among patients whose valves failed due to stenosis, while patients whose bioprosthetics failed due to a combination of those problems had survival rates in the range of 80% at one year.

One of the key findings, Dvir observed, was a high proportion of elevated postprocedure mean AV gradients. A gradient of greater than >20 mm Hg was seen in almost 30% of patients, and almost 3% of patients had postprocedure gradients >40 mm Hg.

Delving deeper into this issue, Dvir and colleagues identified valve stenosis or a combination of stenosis and regurgitation as key predictors of postprocedure AV gradients >20 mm Hg. Of note, use of a Sapien device, as compared with a CoreValve device, also doubled the likelihood of this degree of impaired flow post-TAVI.

"We have to understand that these two devices . . . are very, very different," Dvir told a morning press conference. "One of the most basic differences between the devices is that the functional part of the Edwards valve is at the level of the annulus of the native valve, whereas the CoreValve is 5 to 10 mm—depending on the height of the implantation—above that level. We now understand that the area of the aortic stenosis in the native valve is a very, very problematic area, so we can understand that that same region inside the bioprosthetic valve is even more problematic," as different results for the two types of valves suggest.

Other safety issues emerged, including a 30-day stroke rate of 1.4%, a malposition rate of 11.1%, need for a second TAVI device in 6% of patients, and need for emergent surgery in 1.9%.

Overall, however, the valve-in-valve procedure was effective in the "vast majority" of patients, Dvir said, with 87.5% of patients improving to NYHA class 1 or 2 postprocedure.

Never envisioned 10 years ago

Dr Alain Cribier

Commenting on the study results, **Dr Alain Cribier** (University of Rouen, France), who pioneered the first transcatheter valve a decade ago, acknowledged that he'd never envisioned using a TAVI device to treat surgical valve failure. "You can understand that my goal was very, very precise—I just wanted to avoid valvular restenosis after balloon valvuloplasty, so I was very much [focused on] implanting a valve inside a native valve."

First, he said, researchers needed to prove a TAVI valve could work. "Then, when we saw it working so well in the native valve, people started thinking that it might also be useful in valve-in-valve."

This is an excellent new indication, said Cribier, "but we are using the wrong tools." He pointed to the size mismatch between the internal diameter of the surgical valves and the external diameter of the TAVI devices, and the underexpansion and malposition as factors that needed to be improved.

"So I am not at all surprised that we have some residual gradient and some issues like aortic regurgitation and strokes, because these devices are not really adapted to what we want to do. Both companies today are developing new devices that are aimed directly at treating the valve-in-valve issue."

Related link

- Valve-in-valve technique fixes leaks after TAVI
  [*Interventional/Surgery > Interventional/Surgery*, Feb 23, 2011]