Transcatheter aortic valve implantation: expansion and overexpansion

Transcatheter aortic valve implantations (TAVI) quickly progressed from a 2002 proof of principle, through clinical trial successes, to various regulatory approvals. Today physicians around the globe treat TAVI as standard of care, and increasing variety of devices are hitting the market. But the stunning success and subsequent spread have put it at risk of overuse, some critics charge.

Several trials have shown that TAVI holds significant advantages for patients with aortic stenosis who cannot undergo surgery. In 2010, for example, the US-based Placement of Aortic Transcatheter Valves (PARTNER) trial revealed that TAVI patients had a 20% survival advantage over medical therapy. The following year, further PARTNER trial results showed that patients at high-risk for complications—even those who could have surgery—also stood to benefit from the less invasive TAVI procedure. A 2015 follow-up study showed that the results endured over time, with a significant reduction in mortality risk for TAVI patients compared to standard care at five years out. Other trials in Europe and elsewhere supported these findings.

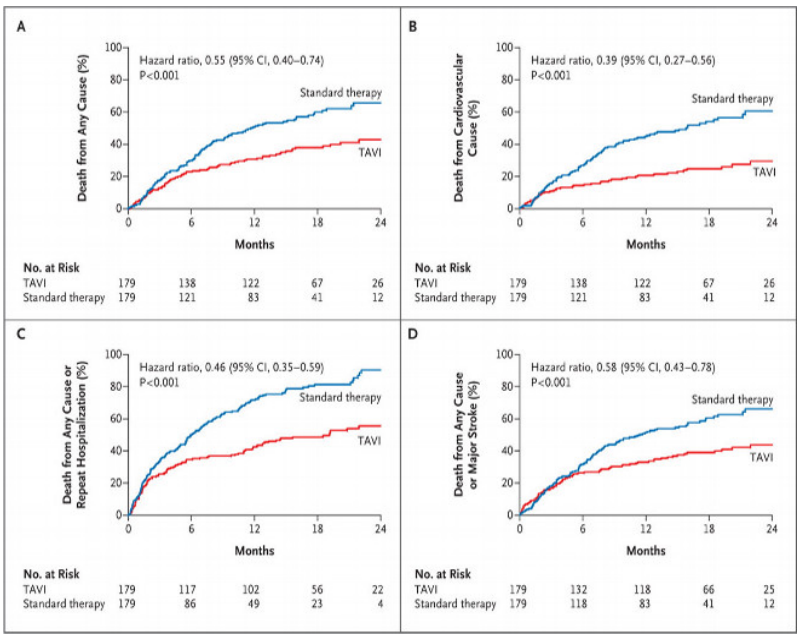
Moreover, a typical TAVI patient has a significantly shorter hospital stay and a quicker return to mobility, making it a popular choice for patients.

The clinical outcomes led to regulatory success. The balloon expandable Edwards SAPIEN (Edwards Lifesciences Inc, Irving CA) device, which was used in the first TAVI implantation in 2002, earned a European CE Mark in 2007 and approval from the US FDA in 2011. Medtronic's CoreValve won its CE Mark in 2012. The FDA approved it for extreme risk patients in January 2014 and lowered the bar to high-risk in June 2014. Many more devices are chasing the market.

Use has expanded accordingly. Estimates say there were only 7000 TAVI patients in 2011, but that jumped to 50,000 in 2012, and 80,000 by 2013. Last year, Medtronic claimed that its CoreValve patients alone numbered over 60,000.

But some doctors warn that, as younger and intermediate risk patients are included as TAVI candidates, use is becoming excessive. Markus Krane, a cardiovascular surgeon at the German Heart Center in Munich, cites two potential problems. First, as the procedure becomes more routine, cardiologists tend to carry it out themselves. While most cardiologists are qualified enough to do that, many now do it in the absence of a surgical unit. This is dangerous, given the significant risk of complications such as bleeding, says Krane.

The other problem is durability. The valves only last ten years, and even less in 40- or 50-year-old patients. "That is probably because younger patients are more active, putting more stress on the valve," says Krane. If a patient receives a valve at age 50, he would likely have to have two replacements within the next decades. But with the third one, there may not be enough space for the device. At that point, the patient could not have another TAVI, and, at 70, he might no longer be eligible for surgery, says Krane.



Time-to-Event Curves for the Primary End Point and Other Selected End Points.
Leon MB et al. N Engl J Med 2010;363:1597-1607.
(Permission adapted from NEJM)

Figure 1. Time-to-Event Curves for the Primary End Point and Other Selected End Points. Event rates were calculated with the use of Kaplan–Meier methods and compared with the use of the log-rank test. Deaths from unknown causes were assumed to be deaths from cardiovascular causes.

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