

TAVI, safe and effective as surgical valves at two years in lower risk patients

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Two year outcomes in a study comparing implantation of transcatheter and surgical bioprosthetic aortic valves shows that the less invasive procedure is safe and effective, and comparable to the gold standard, surgical valve replacement, in patients whose operational risk was lower than that of patients studied in the pivotal randomized trials for these new devices.

Dr. Lars Søndergaard from the Heart Center, Rigshospitalet, Copenhagen University Hospital, Denmark presented the results of the Nordic Aortic Valve Intervention (NOTION) trial here today in the opening Hot Line session of EuroPCR 2015.

"The NOTION study is the first randomised clinical trial to include all-comer [patients](#)," Søndergaard said. "Despite the fact that the trial was launched in the early days of [transcatheter aortic valve implantation](#) (TAVI), the two-year data show that the therapy is as efficient and safe as the well-established surgical [aortic valve replacement](#) (SAVR). Although we are still waiting for data on long-term durability of the TAVI prosthesis before routinely offering this new technology to younger patients, the NOTION trial indicates that TAVI can be offered to selected lower risk patients."

The first, large, randomised trials supporting a role for TAVI in patients with [severe aortic stenosis](#) enrolled very high-risk patients, typically with logistical EuroSCOREs of approximately 20 or higher. Recent clinical [trials](#) and registry studies, however, indicate that TAVI is being used

increasingly in patients at lower surgical risk. In one analysis, approximately half of patients enrolled in the major European registries had EuroSCOREs less than 20.

NOTION enrolled patients at three hospitals in Denmark and Sweden, ultimately randomising 139 patients to a self-expanding TAVI device and 135 to a surgical bioprosthesis. Mean EuroSCORE was similar (8.4% for TAVI and 8.9% for SAVR) in the two groups) and 82% of the patients were at low [surgical risk](#) (STS score

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