

Results of the STACCATO Trial reported at TCT 2011

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Researchers leading a clinical trial said that transapical transcatheter aortic valve implantation (a-TAVI) may be inferior to surgical aortic valve replacement (SAVR) in operable elderly patients. However results were only preliminary as the trial was carried out on 70 patients out of a planned 200 before it was terminated early for safety concerns. Results from the STACCATO trial were presented today at the 23rd annual Transcatheter Cardiovascular Therapeutics (TCT) scientific symposium, sponsored by the Cardiovascular Research Foundation.

TAVI has become a [treatment option](#) for patients with [aortic valve stenosis](#), who are not amenable or at high risk to SAVR. The goal of the STACCATO trial was to compare a-TAVI with SAVR in operable elderly patients.

Researchers planned a 1:1 randomization of 200 unselected operable AVS patients with no need for [revascularization](#) and aged ≥ 75 years. The primary endpoint was the composite of death, stroke and/or renal failure at 30 days. Two Danish university centers participated after more than 40 TAVI procedures had been performed with good results at each center.

After inclusion of 70 patients (34 apical TAVI, 36 SAVR), the study was terminated after advice from the Data Safety Monitoring Board, because of an excess of events in the apical TAVI group. Baseline characteristics were similar in the two groups. The primary endpoint was met in five TAVI patients (two deaths, two major strokes, and one case of renal

failure) compared to one stroke in the SAVR group.

"In its present phase of development, transapical transcatheter aortic valve implantation may be inferior to surgical [aortic valve replacement](#) in operable [elderly patients](#)," said Leif Thuesen, MD, the lead investigator of the trial. Dr. Thuesen is from the Department of Cardiology at Aarhus University Hospital in Denmark.

Researchers noted that after study termination, these procedures have been optimized by routine preoperative multi-slice computed tomography (MSCT) assessment and by the availability of the 29 mm valve. Further improvement is likely to take place with improved devices and pre-procedure assessment, they said.

Provided by Cardiovascular Research Foundation

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