Risk of stroke after transcatheter aortic valve implantation (TAVI): a meta-analysis of 10,037 published patients


CRD summary
This review found that transcatheter aortic valve implantation was associated with a stroke rate of 3.3% and a mortality rate of 8.1% in the first 30 days following surgery. While this conclusion summarises the observed event rates, it provides no indication of data quality or completeness. The secondary conclusion about different stroke rates between procedures is not strongly supported.

Authors' objectives
To estimate the incidence of peri-procedural stroke and outcomes in patients undergoing transcatheter aortic valve implantation.

Searching
The MEDLINE database was searched from 2004 up to November 2011 for articles in English; search terms were provided. Reference lists of retrieved articles were handsearched for further articles.

Study selection
Studies of patients undergoing transcatheter aortic valve implantation for native aortic valve stenosis by the transfemoral, transaxillary/trans-subclavian or transapical routes were eligible for inclusion. Studies had to report the rate of stroke and/or transient ischaemic attack. Case studies were excluded.

In included studies, patients underwent transfemoral, transapical or trans-subclavican transcatheter aortic valve implantation. Valve devices and access sites used included Medtronic/CoreValve ReValving System transarterial (transfemoral and transaxillary/subclavian), Edwards SAPIEN transarterial and Edwards SAPIEN transapical, where reported. The mean age of included patients was 81.5 years (range 74.6 to 85.0 years); 53.1% (range 0 to 77%) were women. The mean logistic EuroSCORE (European System for Cardiac Operative Risk Evaluation) was 24.77% (range 12.3 to 44.2%), which showed a high risk of operative mortality.

Studies defined transient ischaemic attack as any reversible neurological deficit with a duration shorter than 24 hours. Procedural stroke/transient ischaemic attack were defined as any neurological event occurring within 24 hours after the procedure.

The authors did not state many reviewers performed the study selection.

Assessment of study quality
The authors did not state that they assessed study quality.

Data extraction
Study definitions of stroke or transient ischaemic attack were not re-adjudicated; any stroke or transient ischaemic attack reported in a given published study was considered to be an event. Rates of events were defined as the number of events divided by the number of treated patients with available data.

The authors did not state how many reviewers performed the data extraction.

Methods of synthesis
A statistical synthesis was conducted. Event rates from individual studies were combined into a weighted average, weighted by sample size. Outcomes were reported as means and standard deviations.

Results of the review
Fifty-three studies including 10,037 patients were included in the review.
Procedural stroke (within 24 hours of the transcatheter aortic valve implantation procedure) occurred in 1.5±1.4% of patients.

During the first thirty days after the aortic valve implantation procedure, the rate of stroke or transient ischaemic attack was 3.3±1.8%; most were major strokes (2.9±1.8%). During the first year after the aortic valve implantation, the stroke or transient ischaemic attack rate was 5.2±3.4%. Differences in stroke rates were associated with different surgical approaches and types of valve prostheses; the lowest stroke rates were observed following transapical transcatheter aortic valve implantation (2.7±1.4%; 2,482 patients), but differences between surgical approaches were small with overlapping confidence intervals.

Mortality within 30 days after the procedure was 8.1±3.9%. For patients who experienced stroke, 30-day mortality was 25.5±21.9% compared with 6.9±4.2% in those did not experience stroke.

**Authors' conclusions**
Transcatheter aortic valve implantation was associated with a 30-day transient ischaemic attack or stroke rate of 3.3±1.8%. Most of these were major strokes and were associated with increased mortality (one in four patients) in the first 30 days following the procedure.

**CRD commentary**
The aim and inclusion criteria for the review were clear. The search was limited to one database, with no attempt to retrieve grey literature or publications in other languages than English. Therefore, the review was open to publication and language bias; relevant papers may have been missed. The review process was poorly-reported, which made it difficult to judge whether there were attempts to minimise reviewer error and bias.

No assessment of study quality was reported and, although details of included patients were provided, no information was given on study design. This meant it was not possible to judge the quality and reliability of the evidence base. The statistical synthesis seemed appropriate.

While the authors’ main conclusion reasonably summarises event rates from the included data, they provide no indication of the quality or completeness of this data. Their secondary conclusion that there were differences in stroke rates between different surgical approaches and valve prostheses does not appear to be strongly supported by the evidence.

**Implications of the review for practice and research**
**Practice:** The authors stated that the higher stroke risk observed with transcatheter aortic valve implantation compared with medical treatment of high-risk patients with symptomatic aortic stenosis should not be perceived by physicians as prohibitive for referring appropriate patients for this procedure, given the unequivocal improvement in functional status and mortality with this procedure compared with those managed medically.

**Research:** The authors stated that future research should identify the underlying risk factors and mechanism of stroke so that appropriate strategies may be designed and evaluated to improve this risk with the newer procedure. Large carefully designed registries were needed to evaluate the risk factors for stroke with transcatheter aortic valve implantation. The impact of different antithrombotic regimens and the efficacy/effectiveness of cerebral embolic protection devices in reducing the risk of stroke in transcatheter aortic valve implantation patients remained undetermined.

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**Bibliographic details**

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This is a critical abstract of a systematic review that meets the criteria for inclusion on DARE. Each critical abstract contains a brief summary of the review methods, results and conclusions followed by a detailed critical assessment on the reliability of the review and the conclusions drawn.