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Meta-Analysis Comparing the Frequency of Stroke After Transcatheter Versus Surgical Aortic Valve Replacement

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Abstract

Stroke is one of the most feared complications of aortic valve replacement. Although the outcomes of transcatheter aortic valve implantation (TAVI) improved substantially over time, concerns remained about a potentially higher incidence of stroke with TAVI compared with surgical replacement (SAVR). However, comparative data are sparse. We performed a meta-analysis comparing the incidence of stroke among patients undergoing TAVI versus SAVR. Of the 5067 studies screened, 28 eligible studies (22 propensity-score matched studies and 6 randomized trials) were analyzed. Primary endpoints were 30-day stroke and disabling stroke. Secondary endpoints were 1-year stroke and disabling stroke. A total of 23,587 patients were included, of whom 47.27% underwent TAVI and 52.72% underwent SAVR. For each endpoint, pooled estimates of odds ratio (OR) with 95% confidence interval (CI) were calculated. The pooled estimates for stroke (2.7% vs 3.1%, OR 0.86; 95% CI 0.72 to 1.02; p=0.08) and disabling stroke (2.5% vs 2.9%, OR 0.96; 95% CI 0.57 to 1.62; p=0.89) were comparable following TAVI versus SAVR at 30 days. Similarly, the pooled estimates for stroke (5.0% vs 4.6%, OR 1.01; 95% CI 0.79 to 1.28; p=0.96) and disabling stroke (4.1% vs 4.5%, OR 0.92; 95% CI 0.92 to 1.39; p=0.71) were similar at 1 year. A sensitivity analysis including only RCTs yielded similar results. Our meta-analysis documents comparable rates of strokes and disabling strokes following TAVI or SAVR both at 30 days and 1 year.

The introduction of transcatheter aortic valve implantation (TAVI) and the continuous improvement in the outcomes of surgical aortic valve replacement (SAVR) have revolutionized the treatment of severe aortic stenosis in the last decade.[1] However, stroke

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Disclosures

Supplementary materials

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remains one of the most feared and unresolved devastating complications of TAVI and SAVR.[2,3] Although the interest in postprocedural stroke in patients undergoing TAVI or SAVR is growing, comparative studies between the two modalities are sparse.[2,4] We performed a comprehensive systematic review and a meta-analysis of the published studies to compare the incidence of stroke and disabling stroke at 30 days and 1 year among patients undergoing TAVI and SAVR.

Methods

Our review protocol was conducted in accordance with PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) reporting guidelines (Supplementary Protocol). We conducted a literature search in PUBMED, MEDLINE, EMBASE, EBSCO, CINAHL, Web of Science, and Cochrane (January 2, 2018) to identify eligible studies using the Medical Subject Headings search terms and text word search. The data were independently extracted by authors (T.B. and K.S.). Disagreements were resolved through consensus and arbitration by author (M.A.). Studies were included if they were (1) randomized controlled trials (RCTs) and propensity-matched prospective (PSM) observational studies comparing TAVI and SAVR, (2) published in peer-reviewed journals, (3) had follow-up of at least 30 days, and (4) reported stroke and/or disabling stroke as a clinical endpoint. Exclusion criteria included observational studies reporting nonpropensity matched populations and nonpublished studies (abstracts). The study characteristics extracted were the year of publication, study design, the number of patients, clinical characteristics, confounding factors, comparability between groups at baseline, outcomes, and study follow-up. The main outcomes of interest between the two interventions in this study included 30-day stroke and disabling stroke and 1-year stroke and disabling stroke.

The meta-analyses were performed using Comprehensive Meta-Analysis version 2.0 (Biostat, www.meta-analysis.com). For each clinical endpoint, pooled estimates of odds ratio (OR) with 95% confidence interval (CI) were calculated using the random effects model with the Mantel-Haenszel (MH) method. Heterogeneity among individual study effect sizes was examined using the I^2 index, tau-squared, and the Q-test p value. Publication bias was assessed using funnel plots and Egger's linear regression test of funnel plot asymmetry (Supplementary eFigure 1). Pooled estimates were displayed with 95% CI values and were considered statistically significant at $p<0.05$. A subanalysis was performed comparing stroke rates after TAVI or SAVR in subgroups of patients (low-to-inter-mediate risk and high risk). A sensitivity analysis was performed including RCT only.

Results

A total of 5067 potentially relevant citations were screened (Figure 1). After removal of duplicate and nonrelevant studies, we retrieved 76 full-text articles for evaluation, of which 28 satisfied the selection criteria. A total of 22 PSM observational studies and 6 RCTs were included in the meta-analysis (Table 1).[3,5–31] All eligible studies were in the English language. Table 1 summarizes the baseline characteristics of the patients in the included studies. The 28 studies enrolled a total of 23,587 patients; 11,150 (47.27%) in the TAVI group and 12,437 (52.72%) in the SAVR group. Sample sizes ranged from 28 to 4732

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patients. Although most studies involved patients at a high surgical risk, 2 RCTs and 6 PSM observational studies included patients at low-to-intermediate surgical risk. Detailed baseline characteristics of individual studies included in our meta-analysis are illustrated in Supplementary eTable 1.

Meta-analysis of RCT and PSM studies

There was no statistically significant difference in 30-day stroke between TAVI and SAVR (2.7% vs 3.1%, OR 0.86; 95% CI 0.72 to 1.02; p=0.08; I^2=3.019%; Figure 2). Of the total 28 studies included in the analysis, 8 studies (4 RCTs and 4 PSM observational studies; 3086 TAVI patients; 2998 SAVR patients) reported the rate of disabling stroke at 30 days, which was not statistically different following TAVI versus SAVR (2.5% vs 2.9%, OR 0.96; 95% CI 0.57 to 1.62; p=0.89; I^2=42.81%; Figure 3). The incidence of all strokes at 1 year was similar in patients who underwent TAVI or SAvR (9 studies [5 RCtS and 4 PSM studies]; 16,544 total patients; 5.0% vs 4.6%, OR 1.01; 95% CI, 0.79 to 1.28; p=0.96; I^2=46.94%; Figure 4). There were no PSM studies that reported disabling stroke at 1 year, and hence, only RCTs were included in the analysis. In a secondary analysis of low-to-intermediate risk patients and high-risk patients, there was still no difference in the incidence of stroke or disabling strokes at 30 days and 1 year between TAVI and SAVR in both cohorts (Supplementary eFigures 2-5).

Meta-analysis of RCT only

In a sensitivity analysis excluding PSM studies and including RCTs only, similar rates of stroke were observed at 30-day follow-up after TAVI vs SAVR (6 RCTs, 5488 patients, 4.4% vs 5.2%, OR 0.86; 95% CI 0.61 to 1.2; p=0.41; I^2=33.2%; Figure 5). Rates of disabling stroke at 30 days were also similar (4 RCTs, 5138 patients, 2.7% vs 3.2%, OR 0.90; 95% CI 0.52 to 1.53; p=0.684; I^2=55.3%; Figure 5). Similarly, rates of stroke at 1 year (5 studies; 5418 patients; 6.6% vs 7.3%, OR 0.90; 95% CI 0.66 to 1.2; p=0.53; I^2=45.3%) and disabling stroke (4 studies; 5138 patients; 4.1% vs 4.6%, OR 0.93; 95% CI 0.62 to 1.4; p=0.71; I^2=48.5%) were not different between patients undergoing TAVI and those undergoing SAVR (Figure 6).

Discussion

Stroke is a potentially devastating consequence of aortic valve replacement, regardless of the replacement method. Postoperative stroke has been associated with a significantly increased risk of morbidity, mortality, and resource utilization following both transcatheter and SAVR.[32] In the early experience with TAVI, concerns were raised about an excess rate of stroke with this technology compared with the traditional surgical aortic valve replacement; in the PARTNER trial (cohort A), there was a twofold higher stroke rate in the TAVI group compared with the SAVR group (4.6% vs 2.4%, p=0.07).[5] However, neurologic outcomes were ascertained by a Clinical Events Committee chart review and not with neurologist-adjudicated testing. In the Pivotal CoreValve trial, no differences between TAVI and SAVR with regard to 30-day incidence of stroke were seen.[7] Although both trials utilized first-generation transcatheter heart valves, these differences in neurologic outcomes were attributed to (1) prospective ascertainment of neurologic events with neurologist-adjudicated

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testing for all patients and (2) the inclusion of generally lower risk cohorts in the CoreValve trial compared with the PARTNER trial.[7]

Subsequent to the publication of these two pivotal trials, several RCTs and a large number of cohort studies have been published with variable reported incidence of stroke following surgical or transcatheter aortic valve replacement (see Supplementary Materials). However, uncertainties persisted regarding the differential impact of the replacement approach (transcatheter vs surgical) due to the variable definitions and reporting methodologies of stroke across the studies. Therefore, in this meta-analysis, we sought to assess the pooled incidence of two hard endpoints (stroke and disabling stroke) following SAVR or TAVI. To our knowledge, this is the largest study to date (23,587 patients) aiming to synthesize the best available evidence on stroke following aortic valve replacement in contemporary practice.

Our analysis reveals several intriguing findings. First, we found no significant difference between SAVR and TAVI with regards to the incidence of stroke at 30-day and 1-year follow-up. These findings were persistent in the overall cohort including RCTs and PSM studies, and when only RCTs were included. These findings confirm that in both controlled study and real-world settings, neither SAVR nor TAVI has been found to be a superior approach with regards to early or late stroke events. Whether this will persist in future studies including the latest generation transcatheter heart valves, those involving low-risk patients, and those utilizing cerebral embolic protection devices remain to be seen. Second, likewise, no differences were found between SAVR and TAVI in the 30-day and 1-year incidence of disabling stroke, confirming the equivalence between the two treatment modalities across a wide spectrum of stroke severity. Third, the reported incidences of stroke and disabling stroke were persistently greater in RCT than in PSM analyses, likely due to the protocoled assessment and adjudication of neurologic events in most RCTs. Last, there was a variable but persistent incremental increase in both stroke and disabling stroke events between 30-day and 1-year follow-up. There is a growing interest in improving post-TAVI neurologic outcomes, but most efforts are focused on strategies to minimize the short-term risk of stroke including testing various cerebral embolic protection devices, and optimizing peri-procedural antithrombotic management. However, this finding emphasizes the equally important knowledge gap surrounding preventative strategies that minimize the risk of stroke beyond the 30-day mark. This is no small task as establishing the definitive etiology of late strokes is rather complex in patients with typical risk factors for stroke (hypertension, diabetes, atrial fibrillation, carotid disease, and so on), and post-procedural factors that are often missed or are difficult to diagnose (new onset atrial fibrillation, leaflet thrombosis, and so on).

This is a study-level meta-analysis, and hence, the effect of individual baseline characteristics on the outcomes cannot be thoroughly assessed. Also, significant variability in the definition and ascertainment of stroke were noted. However, we only included RCTs and PSM analyses with similar intrastudy definitions of stroke and disabling stroke. In addition, the results of our meta-analysis persisted in a sensitivity analysis including RCTs only, and in subanalyses of low-to-intermediate risk and high-risk patients, further confirming the validity of our results.

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Postoperative stroke remains one of the most clinically detrimental consequences of both TAVI and SAVR. Based on this meta-analysis, there was no difference in early or late stroke or disabling stroke rates in patients undergoing either TAVI or SAVR. Neuroprotective strategies newer generation devices and improved long-term secondary stroke prevention may help improve cerebral complication rates.

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

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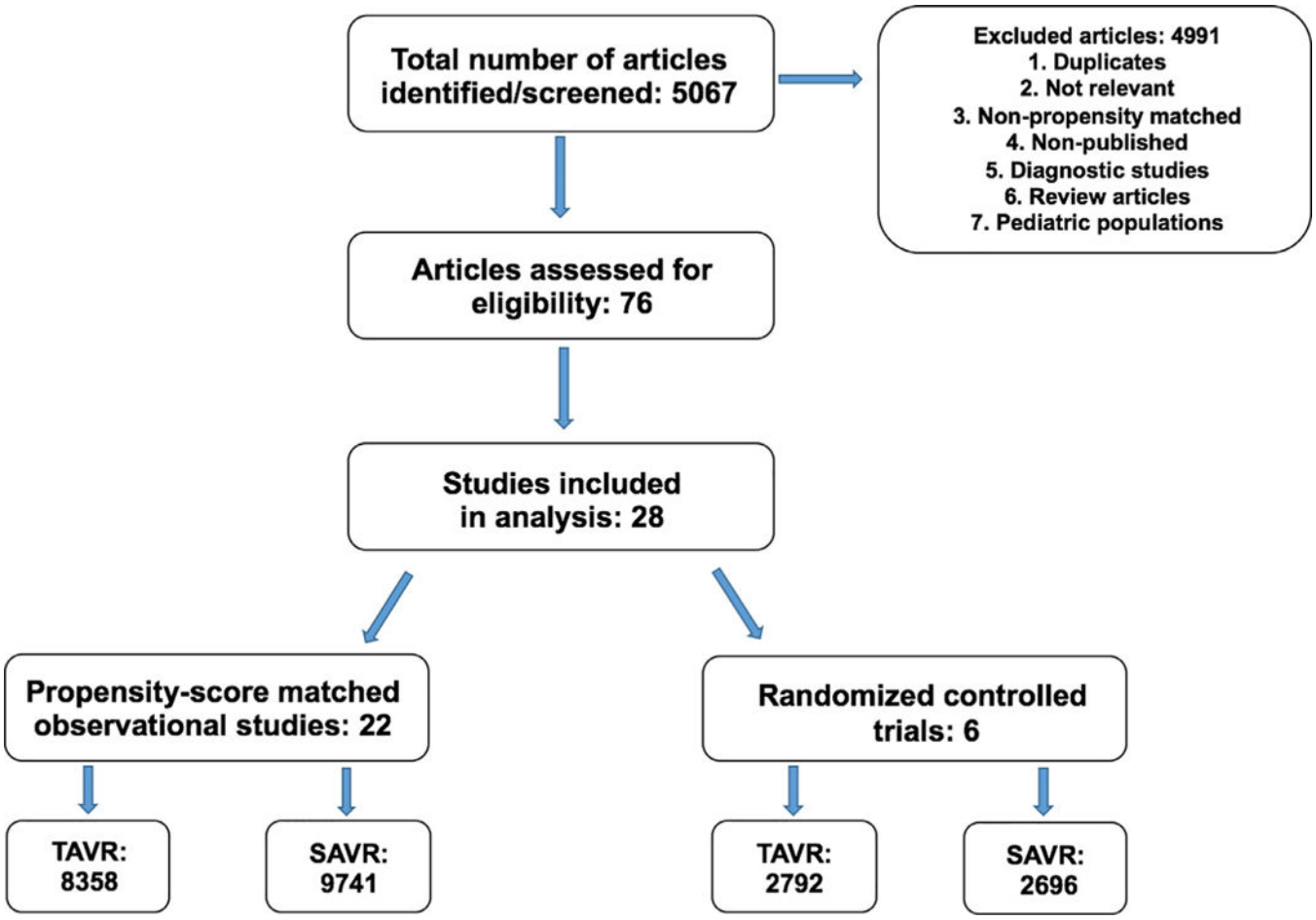

Figure 1.
Flow chart of the meta-analysis.

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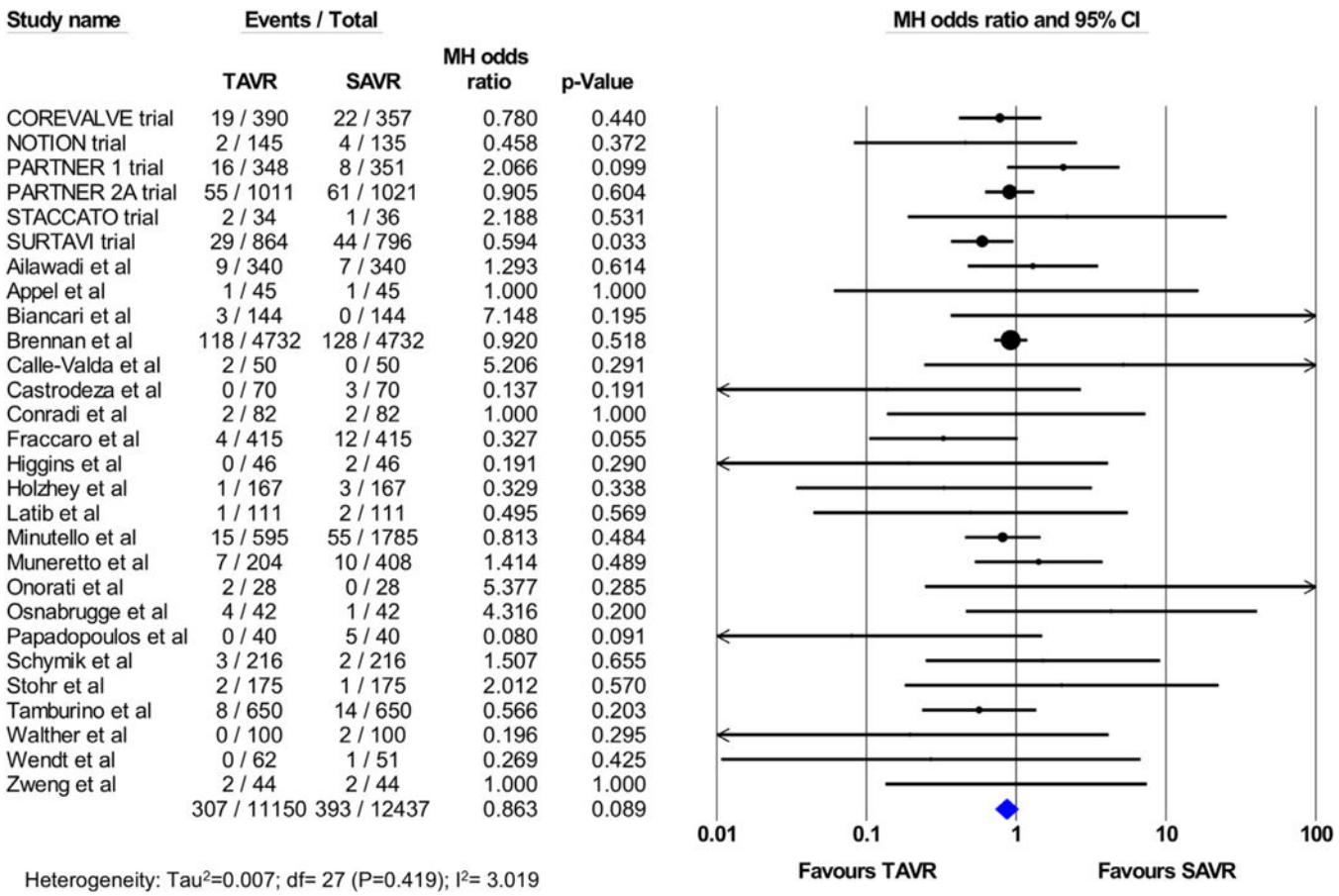

Figure 2.

Pooled effect estimates for the risk of stroke at 30-day follow-up according to the type of aortic valve replacement procedure.

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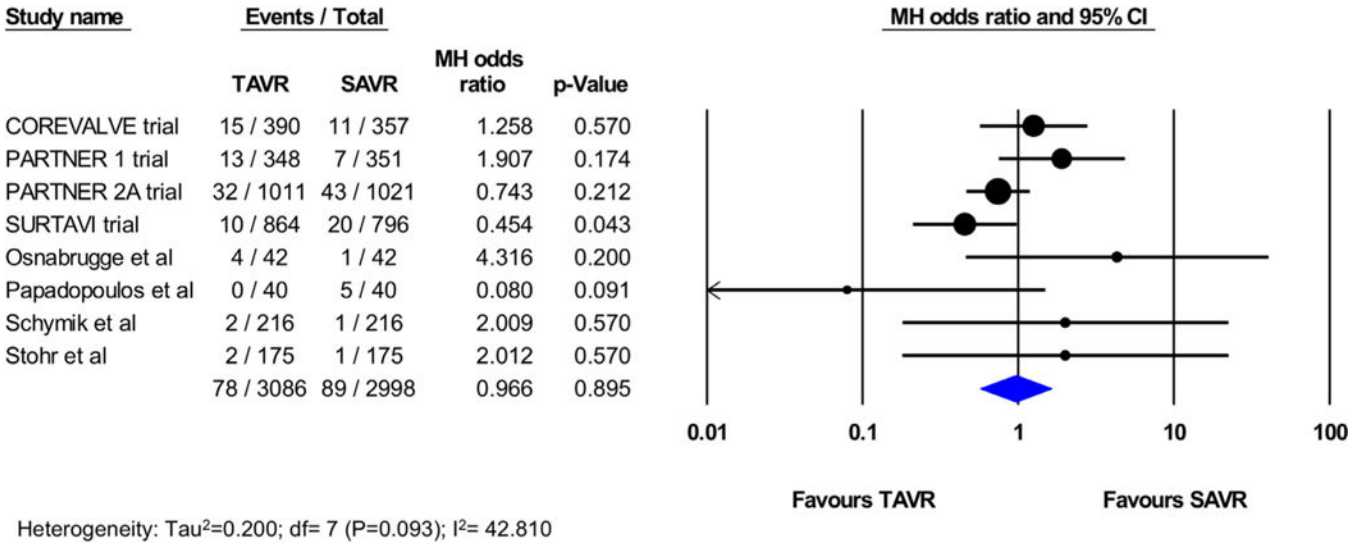

Figure 3.

Pooled effect estimates for the risk of disabling stroke at 30-day follow-up according to the type of aortic valve replacement procedure.

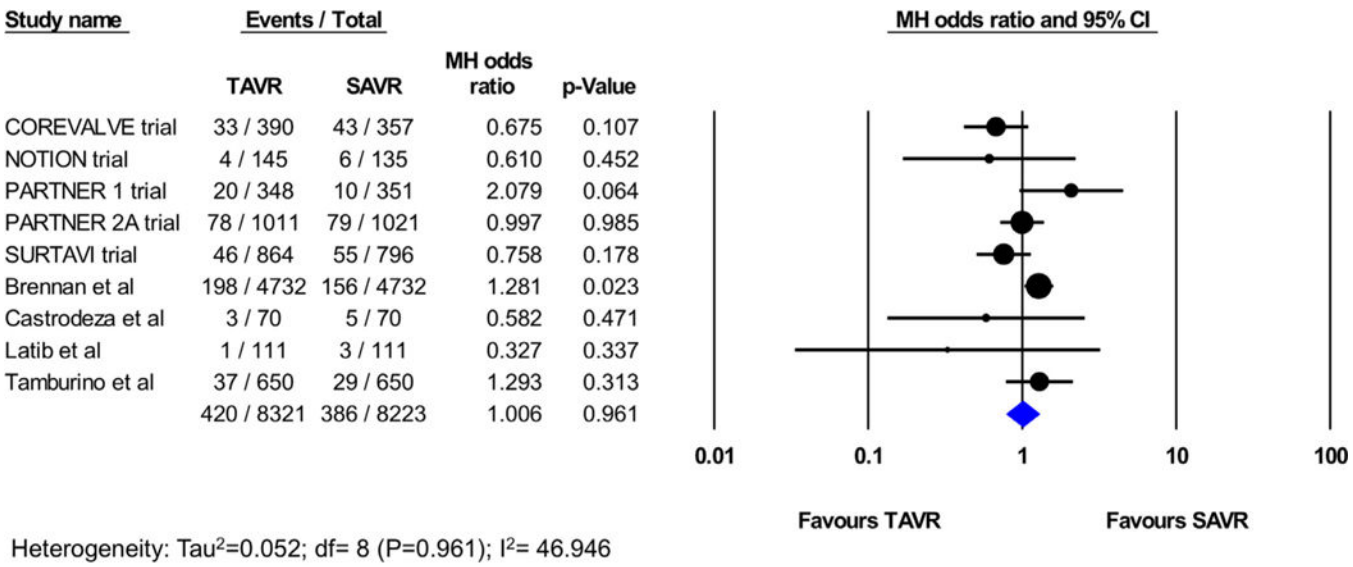

Figure 4.

Pooled effect estimates for the risk of stroke at 1-year follow-up according to the type of aortic valve replacement procedure.

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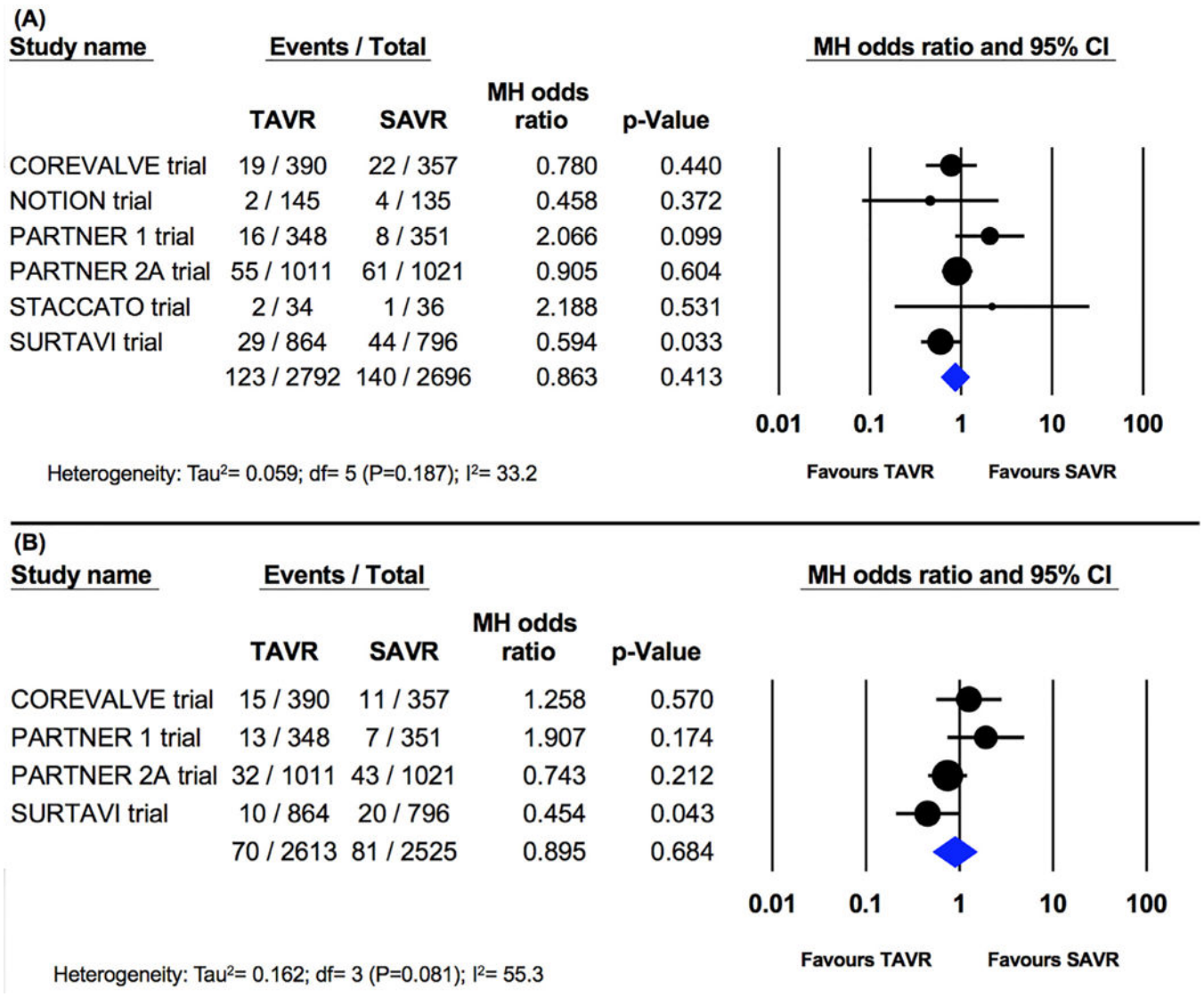

Figure 5.

Pooled effect estimates for the risk of stroke at 30-day and 1-year follow-up according to the type of aortic valve replacement procedure in the randomized controlled trials.

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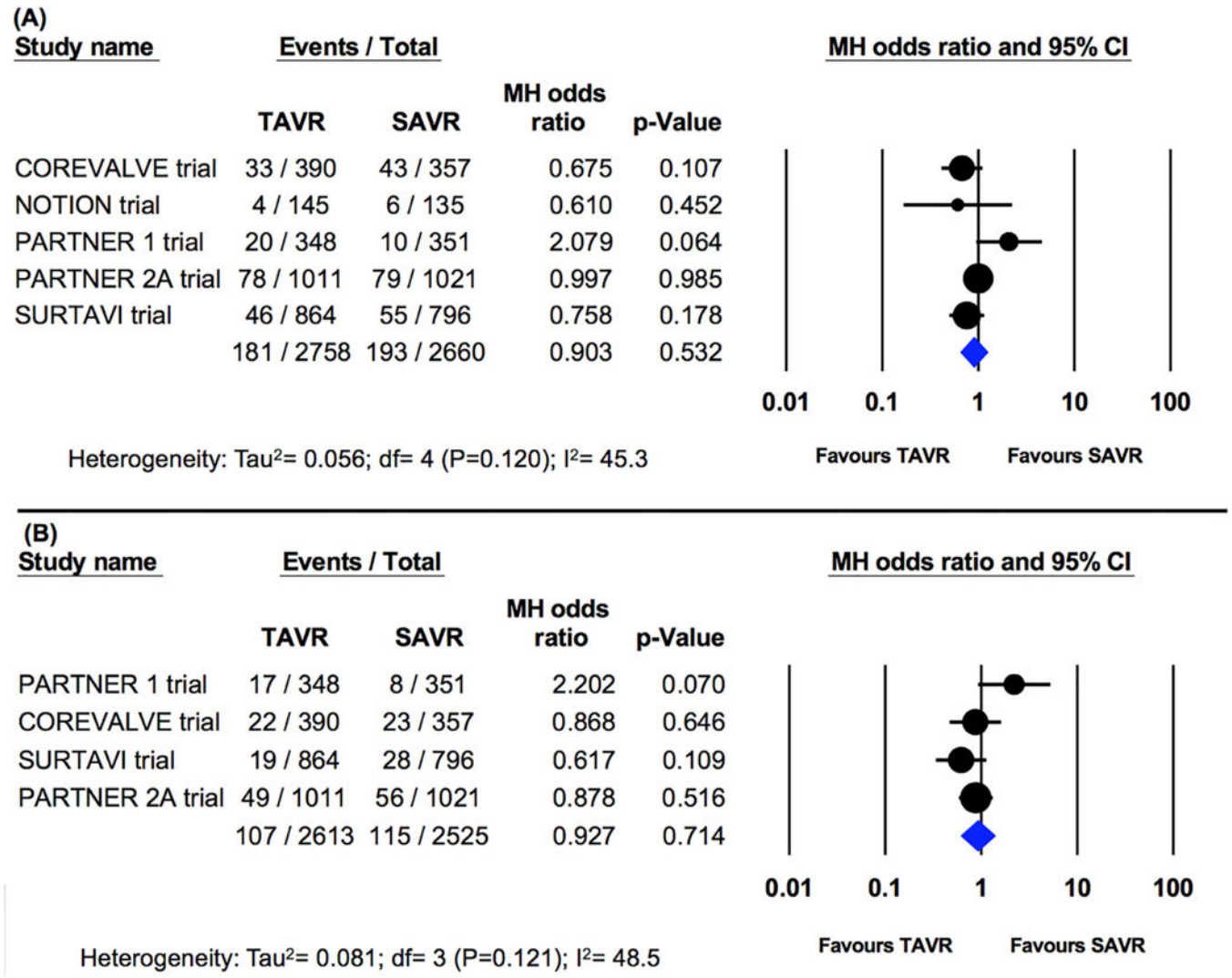

Figure 6.

Pooled effect estimates for the risk of disabling stroke at 30-day and 1-year follow-up according to the type of aortic valve replacement procedure in the randomized controlled trials.

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Table 1

Baseline characteristics of the patients included in the meta-analysis

Baseline characteristics	TAVI (N=11,150)	SAVR (N=12,437)	p Value
Age (years)	80.7 ± 1.8	80.2± 2.8	0.37
Men	47.6%	47.2%	0.89
Coronary artery disease	51.7%	51.1%	0.94
Chronic kidney disease (GFR<60 mL/min)	19%	17.5%	0.81
Diabetes mellitus	27.4%	27.8%	0.89
Atrial fibrillation	29.3%	29.4%	0.98
Chronic obstructive pulmonary disease	22.2%	21.5%	0.81
Hypertension	78.1%	78.1%	0.99
Frailty	25.9%	26.8%	0.96
Hypercholesterolemia	55.0%	51.6%	0.72
Left ventricular ejection fraction	56.1±6.8	54.9±9.3	0.69
Liver disease	6.7%	4.6%	0.55
Pulmonary hypertension	21.9%	20.9%	0.88
Peripheral vascular disease	22.5%	22.2%	0.95
Prior stroke or transient ischemic attack	15.3%	15.5%	0.96
NYHA III or IV	71.7%	71.3%	0.93
Prior myocardial infarction	15.9%	15.3%	0.84
Prior coronary artery bypass graft	31.7%	23.0%	0.37
Prior percutaneous coronary intervention	24.1%	19.3%	0.21
STS score	7.2±3.6	6.2±2.5	0.38
Euro score	17.0±8.3	15.5±7.1	0.52

GFR = glomerular filtration rate; NYHA = New York Heart Association; STS = Society of Thoracic Surgeons; SAVR = surgical aortic valve replacement; TAVI = transcatheter aortic valve implantation.