

# Meta-analysis Evaluating the Safety and Efficacy of Transcarotid Transcatheter Aortic Valve Implantation



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**We performed a systemic review and meta-analysis of studies evaluating transcarotid vascular access for transcatheter aortic valve implantation (TAVI). Published studies evaluating transcarotid vascular access for TAVI were included in this analysis. Outcomes of interest included 30-day mortality, stroke/transient ischemic attack (TIA), new pacemaker implantation, acute kidney injury (AKI), major vascular complication, major bleeding, and myocardial infarction. Pooled estimate for 30-day mortality was 5.3% (95% confidence interval [CI] 4.0% to 6.8%;  $I^2 = 4\%$ ), stroke/TIA was 3.4% (95% CI 2.4% to 4.6%;  $I^2 = 0\%$ ), new pacemaker implantation was 15.3% (95% CI 10.8% to 19.7%;  $I^2 = 72\%$ ), AKI was 3.4% (95% CI 1.3% to 6.5%;  $I^2 = 58\%$ ), major vascular complication was 2.4% (95% CI 1.1% to 3.7%;  $I^2 = 46\%$ ), major bleeding was 4.3% (95% CI 2.8% to 6.1%;  $I^2 = 11\%$ ), and myocardial infarction was 1.1% (95% CI 0.4% to 2.0%;  $I^2 = 0\%$ ). Metaregression was carried out to study the association of effect size with the continuous study-level covariates that included average age, proportion of males, and mean STS score. In this regard, mean STS score showed association with major vascular complications (coefficient: 0.008;  $p = 0.049$ ). Cumulative meta-analysis carried out showed that there was temporal trend of decreasing incidence of stroke/TIA, major vascular complications, and AKI for transcarotid TAVI. In conclusion, transcarotid access for TAVI is a reasonable choice in patients requiring alternate access to transfemoral route. © 2019 Elsevier Inc. All rights reserved. (Am J Cardiol 2019;124:1940–1946)**

Percutaneous transfemoral arterial access is the main route for valve delivery in patients who underwent transcatheter aortic valve implantation (TAVI). With contemporary advances in transcatheter valve technology, majority TAVI procedures are currently performed through the transfemoral route. However, a sizable minority (up to 10%) still requires alternative access due to small or severely diseased iliofemoral arterial beds.<sup>1–4</sup> Although transapical access was historically the alternative access of choice, it fell out of favor due to the increased risk of morbidity associated with it. Current alternative access options include axillary, subclavian, direct aortic, suprasternal, transcaval, and carotid access. The latter in particular has gained some attention since its initial description in 2009.<sup>5</sup> The transcarotid route offers a direct route to the aortic valve, shorter total distance, improved movement precision, and stable catheter delivery.<sup>6</sup> In recent years, several reports assessing the safety and feasibility of transcarotid access for TAVI have emerged. However, most of these studies have small sample sizes and differ in methodology and patient characteristics. This has led to considerable variation in findings regarding the usefulness of transcarotid access TAVI and potential adverse outcomes. In this systematic review and meta-analysis, we attempt to provide a holistic

assessment of the safety and efficacy of transcarotid access TAVI by pooling data from all available studies.

## Methods

This meta-analysis conforms to the PRISMA (Preferred Reporting Items for Systematic review and Meta-Analyses) and American Heart Association guidelines for systematic reviews and meta-analyses.<sup>7,8</sup>

The following online databases were searched up till April 2019: MEDLINE, Scopus, and Cochrane CENTRAL. The detailed search strategy used in each database is provided in the supplementary appendix (Table S1). The first TAVI procedure was reported by Cribier et al in 2002,<sup>9</sup> therefore our search was limited to studies published from 2002 onward. No language restrictions were set. In order to cast a broad net, all keywords were searched for in the titles, abstracts, and keywords. Bibliographies of included articles and relevant systematic reviews were also screened. All retrieved articles were transferred to Endnote X7 (Clarivate Analytics, Pennsylvania), and duplicates were identified and removed. Two reviewers (MSU and SN) independently screened the articles first on the basis of titles and abstracts. Full texts were then read to confirm eligibility. Any discrepancies between the 2 reviewers were solved by discussion until consensus was reached.

Studies were eligible for inclusion if they met the following prespecified criteria (1) they were published full texts or abstracts; (2) at least 5 patients were included; (3) patients underwent transcarotid TAVI for aortic stenosis;

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See page 1945 for disclosure information.

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(4) at least one of the prespecified end points for this meta-analysis was reported.

Two reviewers (MSU and FAM) independently extracted data on key baseline characteristics and outcomes onto a pre-designed form. The following were outcomes of interest: 30-day mortality, acute kidney injury (AKI), major bleeding (defined as Thrombolysis in Myocardial Infarction major bleeding or Bleeding Academic Research Consortium  $\geq 2$ ), myocardial infarction, implantation of a new pacemaker, stroke or transient ischemic attack (TIA), and major vascular complications. Outcomes included were defined as reported in the included studies and were consistent with the Valve Academic Research Consortium – 2 (VARC-2).<sup>10</sup>

Statistical analysis was carried out using the OpenMetaAnalyst software. The proportion of patients experiencing an event was calculated for each outcome. These proportions

were then subjected to arcsine transformation and pooled using a random-effects model. This yielded pooled estimates with 95% confidence intervals (CIs). Metaregression was carried out to study the association of effect size with the following continuous study-level covariates: average age, proportion of males, and mean STS score. Leave-one-out sensitivity analysis was carried to evaluate if any single study disproportionately influenced the results. Additionally, cumulative meta-analysis was conducted to study temporal trends.<sup>11</sup> This chronological meta-analysis reveals if there is a consistency (and therefore reliability) in the results of consecutive studies. Heterogeneity was estimated using the  $I^2$  index, and a value of  $I^2 = 25\%$  to  $50\%$  was considered mild,  $50\%$  to  $75\%$  as moderate, and  $>75\%$  as severe heterogeneity.<sup>12</sup> A  $p$  value  $<0.05$  was considered significant in all cases.

### PRISMA Flow Diagram

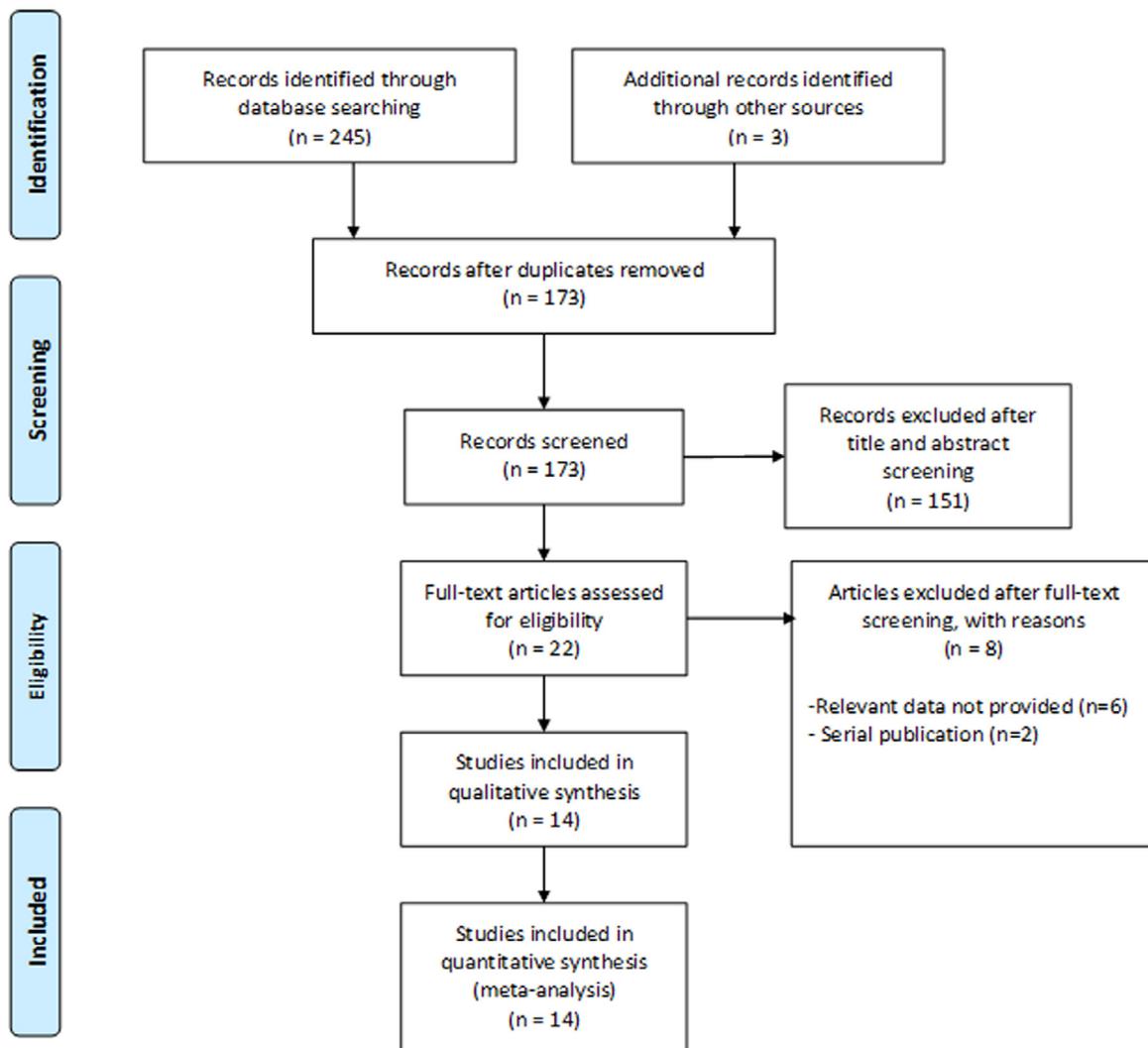


Figure 1. PRISMA flow chart displaying an overview of the literature search.

**Results**

The initial search revealed 248 articles. After removing duplicates, 173 articles remained. Further exclusions based on screening of titles/abstracts (n=151) and full texts (n=8) resulted in a final count of 14 eligible studies in which patients underwent transcatheter aortic valve intervention (TAVI).<sup>13–26</sup> In these, 3 studies conducted a head-to-head comparison of transcatheter aortic valve replacement (TAVR) and transfemoral access for TAVI, and therefore only outcomes of transcatheter aortic valve replacement patients were extracted. The PRISMA flow chart (Figure 1) summarizes the literature search. A total of 1,103 patients were included in the analysis. Mean age of the included patients was 80 years, 53% of them were male, and the mean STS score was 6.8. Detailed study and patient characteristics are presented in Table 1. Details of meta-regression are presented in Table 2.

The summarized results of our meta-analysis are given in the bar graph (Figure 2), which displays the pooled incidence of each outcome along with the corresponding 95% CIs.

Thirty-day mortality (Figure 3) was reported by 13 studies and ranged from 0% to 11.1%. Meta-analysis resulted in a pooled estimate of 5.3% (95% CI 4.0% to 6.8%; I<sup>2</sup> = 4%). Meta-regression revealed that mortality rate was not associated with mean age (coefficient: -0.009; p = 0.321), percentage of males (coefficient: -0.001; p = 0.771) or mean STS score (coefficient: 0.019; p = 0.133). Cumulative meta-analysis (Figure S1) revealed consistency in the findings from studies.

All studies reported the incidence of stroke or TIA (Figure 3). The incidence ranged from 0% to 8.3%, with a pooled estimate of 3.4% (95% CI 2.4% to 4.6%; I<sup>2</sup> = 0%). Upon meta-regression, the rate of post-transcatheter aortic valve replacement stroke/TIA was not associated with mean age (coefficient: -0.009; p = 0.241), percentage of males (coefficient: -0.002; p = 0.160) or mean STS score (coefficient: 0.007; p = 0.526). Cumulative meta-analysis (Figure S2) revealed a chronological trend toward decreasing rates of stroke/TIA with transcatheter aortic valve replacement.

Eleven studies reported the percentage of patients requiring a new pacemaker (Figure 3) after transcatheter aortic valve replacement, which ranged from 6.2% to 27%, with a pooled incidence of 15.3% (95% CI 10.8% to 19.7%; I<sup>2</sup> = 72%). Upon meta-regression, the rate of pacemaker implantation was not associated with mean age (coefficient: 0.005; p = 0.707), percentage of males (coefficient: 0; p = 0.918) or mean STS score (coefficient: -0.017; p = 0.244). Cumulative meta-analysis (Figure S3) revealed consistency in results.

Eleven studies reported the incidence of AKI (Figure 3), and this ranged from 0% to 9.8%, with a pooled estimate of 3.4% (95% CI 1.3% to 6.5%; I<sup>2</sup> = 58%). Upon meta-regression, the incidence of AKI was not associated with mean age (coefficient: -0.005; p = 0.686), percentage of males (coefficient: 0; p = 0.777), or mean STS score (coefficient: 0.011; p = 0.424). Cumulative meta-analysis (Figure S4) revealed a chronological trend toward lower AKI with transcatheter aortic valve replacement.

Thirteen studies reported the incidence of vascular complications post-transcatheter aortic valve replacement (Figure 3). The incidence ranged from 0% to 11.5%, with a pooled estimate of 2.4% (95% CI 1.1% to 3.7%; I<sup>2</sup> = 46%). Meta-regression revealed

Table 1  
Baseline characteristics

Study	Study design	Total sample size	Type of device used	Study design	Males	Mean age (years)	Mean STS score	Prior PCI	Prior CABG	Prior stroke/TIA	Myocardial infarction	Diabetes mellitus	Hypertension	Atrial fibrillation
Modine T., 2012	Prospective	12	Self-expanding	N/A	66%	85	6	N/A	N/A	N/A	N/A	N/A	N/A	N/A
Azmoun A., 2014	Prospective	19	Balloon-expanding (4), Self-expanding (14)	Single Center	74%	82	11.9	37%	32%	N/A	N/A	37%	N/A	63%
Pozzi M., 2015	Prospective	9	Self-expanding	Multicenter	45%	85	7	45%	N/A	N/A	11.1%	11%	100%	45%
Thourani V.H., 2015	Retrospective	11	Balloon-expanding	Single center	45%	69	6	N/A	55%	9%	18%	36%	82%	N/A
Debray N., 2016	Retrospective	174	N/A	Multicenter	55%	81	8.4	21%	20%	14%	N/A	32%	N/A	40%
Mylotte D., 2016	Prospective	96	Balloon-expanding (7), Self-expanding (89)	Multicenter	60%	79	7.1	N/A	18%	10%	17%	32%	N/A	41%
Kallinikou Z., 2017	Prospective	18	Self-expanding	N/A	55%	84	N/A	N/A	11%	N/A	N/A	N/A	N/A	N/A
Kirker E.B., 2017	Retrospective	125	Balloon-expanding	Single center	51%	82	6.0	N/A	30%	11%	N/A	37%	86%	N/A
Chamandi C., 2018	Prospective	101	Balloon-expanding (58), Self-expanding (43)	Multicenter	55%	80	6.6	N/A	24%	16%	N/A	42%	81%	41%
Folliguet T., 2018	Prospective	145	Balloon-expanding (24), Self-expanding (121)	Multicenter	34%	80	N/A	32%	22%	6%	13%	30%	N/A	N/A
Paone G., 2018	Prospective	405	N/A	N/A	50%	79	N/A	N/A	N/A	N/A	N/A	40%	92%	N/A
Watanabe M., 2018	Retrospective	706	Balloon-expanding (353), Self-expanding (353)	Single center	53%	79	6.6	38%	18%	12%	N/A	27%	76%	40%
Allen K., 2019	Prospective	84	Balloon-expanding	Multicenter	55%	79	9	62%	39%	62%	N/A	55%	89%	N/A
Overtchouk P., 2019	Prospective	314	Balloon-expanding	Multicenter	63%	83	5.8	39%	20%	12%	18%	27%	N/A	34%

N/A = Not applicable or not available.

Table 2  
Results of multivariate meta-regression

	Mean age		Percentage of males		Mean STS score	
	Coefficient	p Value	Coefficient	p value	Coefficient	p Value
30-day mortality	-0.009	0.321	-0.001	0.771	0.019	0.133
Stroke/transient ischemic attack	-0.009	0.241	-0.002	0.160	0.007	0.526
New pacemaker implantation	0.005	0.707	0	0.918	-0.017	0.244
Acute kidney injury	-0.005	0.686	0	0.777	0.011	0.424
Major vascular complications	0.008	0.049*	0.001	0.722	0	0.218

\* Significant.

a weak but significant positive association between major vascular complications and mean STS score (coefficient: 0.008;  $p = 0.049$ ). The incidence of vascular complications was not significantly associated with mean age (coefficient: 0.001;  $p = 0.722$ ), or percentage of males (coefficient: 0;  $p = 0.218$ ). Cumulative meta-analysis (Figure S5) revealed a temporal trend toward fewer vascular complications with transcatheter TAVI.

Seven studies reported the incidence of major bleeding (Figure 3), which ranged from 0% to 4.6%, with a pooled estimate of 4.3% (95% CI 2.8% to 6.1%;  $I^2 = 11\%$ ).

Ten studies reported the incidence of myocardial infarction after transcatheter TAVI (Figure 3). The incidence ranged from 0% to 4.2%, with a pooled estimate of 1.1% (95% CI 0.4% to 2.0%;  $I^2 = 0\%$ ).

## Discussion

The main findings of this analysis revealed that the transcatheter access was associated with acceptable short-term morbidity and mortality, suggesting a role for this access route for TAVI in selected patients.

First, the incidence of 30-day mortality in this cohort of intermediate-high risk patients (mean predicted risk of mortality = 6%) was 5.3% (95% CI 4.0% to 6.8%;  $I^2 = 4\%$ ). This mortality rate, albeit higher than what is reported for transfemoral TAVI in contemporary practice, is comparable or lower than what is reported with alternative access TAVI. In the National Inpatient Sample, in-hospital mortality of transfemoral versus transapical TAVI were (4.0 vs 5.4%,  $p = 0.036$ ).<sup>27</sup> In another study including approximately 5,000 Medicare fee-for-service patients between

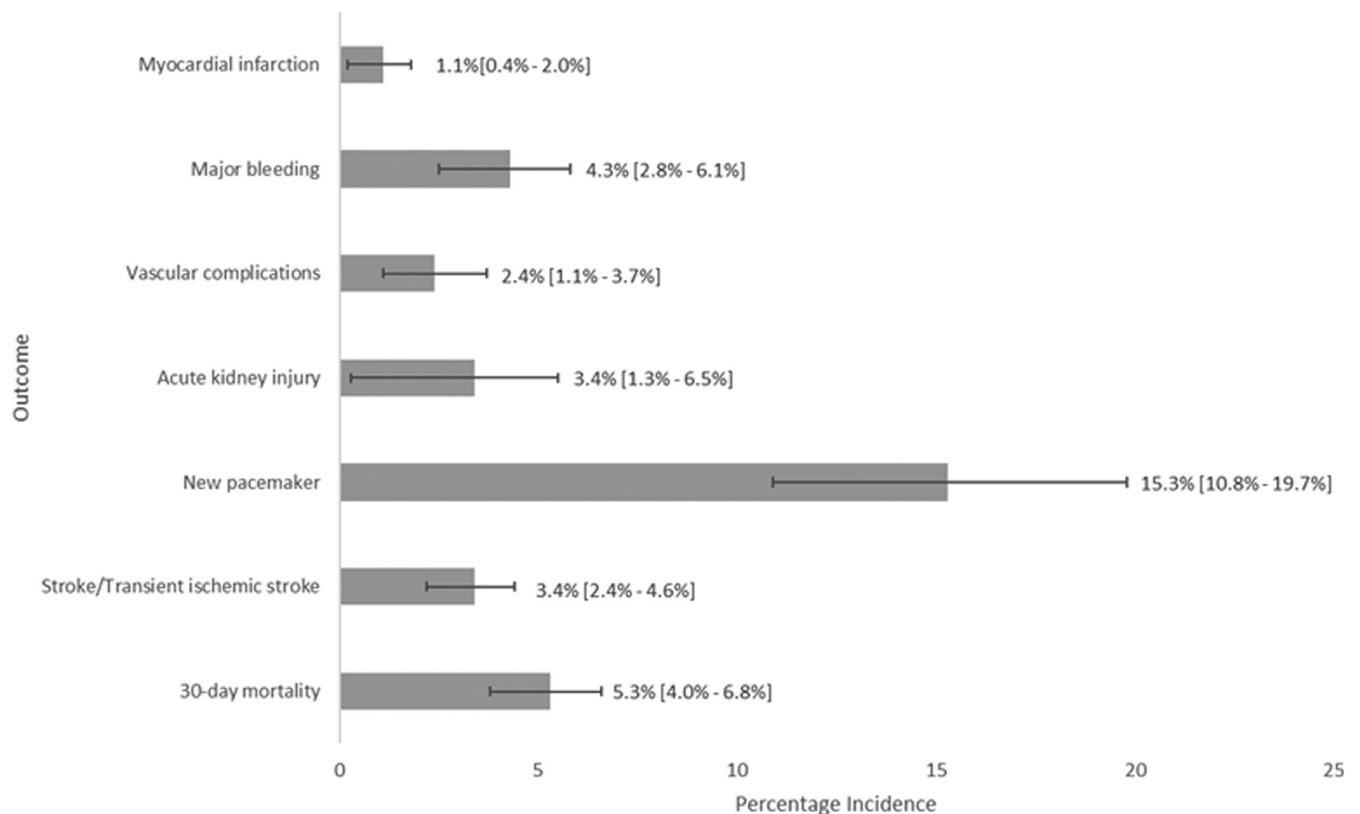


Figure 2. Summarized results of the meta-analysis, displaying the pooled incidence of each outcome.

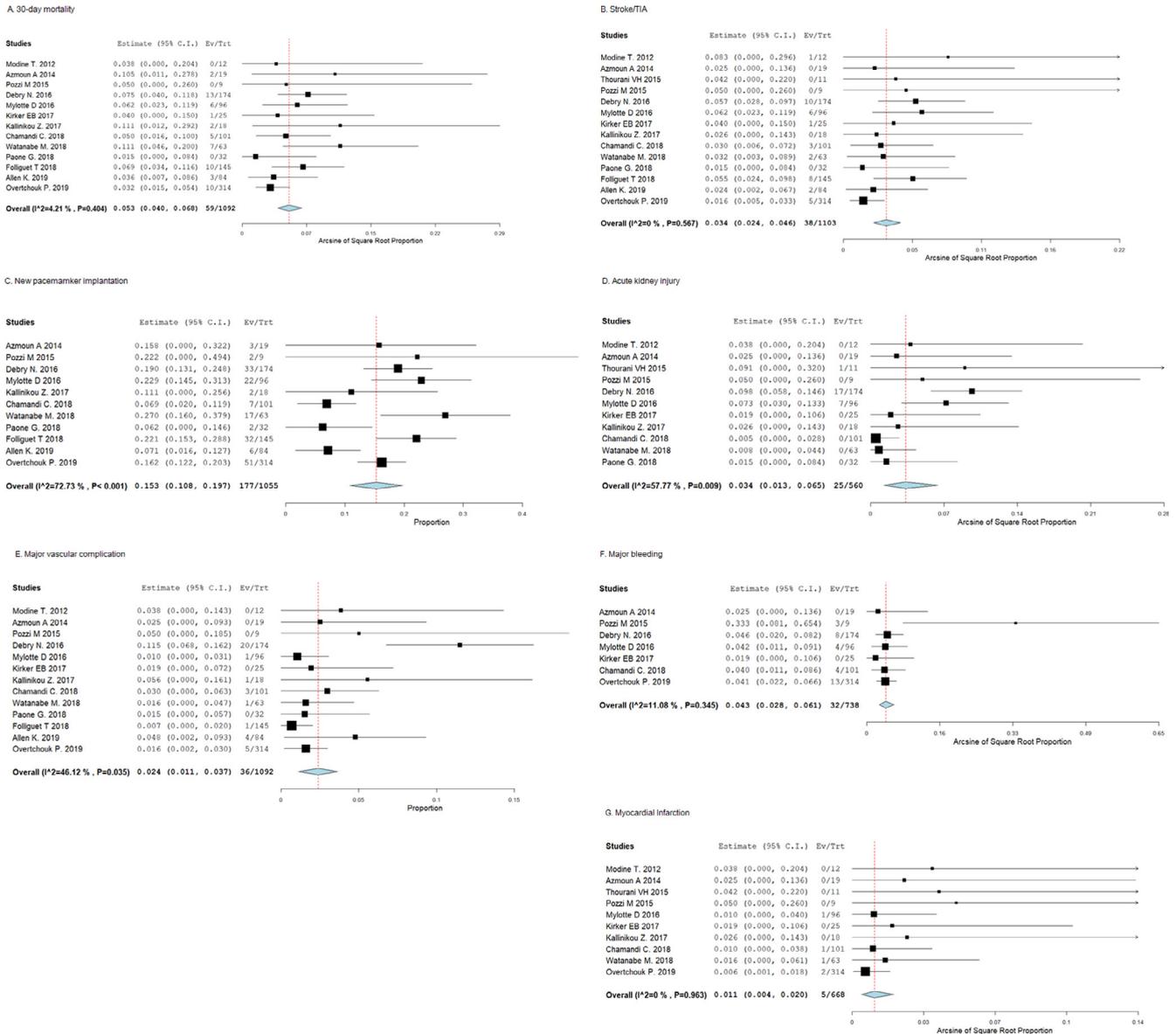


Figure 3. Forest plot displaying the incidence of; (A) 30-day mortality in each study, along with the pooled incidence. (B) Stroke/transient ischemic attack in each study, along with the pooled incidence. (C) New pacemaker implantations in each study, along with the pooled incidence. (D) Acute kidney injury in each study, along with the pooled incidence. (E) Vascular complications in each study, along with the pooled incidence. (F) Major bleeding in each study, along with the pooled incidence. (G) Myocardial infarction in each study, along with the pooled incidence.

2011 and 2012, 30-day mortality rates were higher with transapical and transaortic versus with transfemoral TAVI (9.6% vs 8.0% vs 5.0%, respectively,  $p < 0.001$ ).<sup>28</sup> Similarly, in a large study from the The Society of Thoracic Surgeons/American College of Cardiology Transcatheter Valve Therapy Registry, adjusted 30-day mortality was significantly higher with transaxillary/subclavian TAVI than with transfemoral TAVI (8.4% vs 5.3%,  $p < 0.001$ ).<sup>29</sup> Furthermore, the transcarotid route has been shown to be superior to other alternative access routes during long-term follow-up. In a single center propensity score matched comparison of transcarotid versus transapical and transaortic access for TAVI showed that transcarotid access was associated with a trend toward lower 30-day mortality (3.6% vs 6.3% vs 15.2%;  $p = 0.09$ ), and a significantly higher 2-year

survival rate (88.4% vs 79.2% vs 63.6%;  $p = 0.004$ ), respectively.<sup>30</sup> These findings are in harmony with our study, and suggest that transcarotid access may indeed perform favorably compared with other alternative access routes, and calls for further investigation to identify its role and optimal candidate selection.

For TAVR employing the transcarotid access, stroke remains a major concern due to the proximity of access site to the brain. Our study shows that the pooled estimate of stroke and TIA was 3.4%, which is lower than strokes rates reported in randomized clinical trials (6.4% in PARTNER 2 trial, 4.5% in SURTAVI).<sup>31,32</sup> Indeed, this stroke rate is also significantly lower than what was reported for transaxillary/subclavian access in the Transcatheter Valve Therapy registry (6.3%).<sup>29</sup> Moreover, the cumulative meta-analysis that

we performed showed that with the passage of time, the incidence rates of stroke, and TIA decreased over time. This can be attributed to increase in adaptation of this technique over time and subsequent increase in operator expertise, and also to meticulous screening of patients suitable to this approach.

Another major finding of our analysis points toward lower major vascular complications (pooled estimate 2.4%) when compared with PARTNER 2 trial (7.9%)<sup>31</sup> and SUR-TAVI trial (6%).<sup>32</sup> This could be attributed to the fact that the transcatheter access site corresponds with the direct exposure of the carotid artery, and hence the ability to readily control potential bleeding and/or repair any complications. Our cumulative meta-analysis also revealed that with time, the incidence of these complications saw a further drop, also suggesting a role for learning experience and/or the advances in the TAVI devices and techniques.

Our study had a few important limitations. First, the patients included in this analysis were treated with a mixture of older and newer generation devices and their delivery systems. The impact of this heterogeneity on the outcomes cannot be discounted, and was evident in our cumulative meta-analysis for different outcomes that showed improvement over the course of time. Second, we pooled the data of both balloon and self-expanding valve prosthesis data in this analysis. A comparative analysis between these 2 devices might reveal one to be superior to other in transcatheter access, but this was out of the scope of this study. Lastly, the studies done by Debry et al<sup>22</sup> and Mylotte et al<sup>26</sup> did have the potential of having some overlap in patient population, since they both recruited from Hôpital Cardiologique, Lille during an overlapping time frame.

Transcatheter access for TAVI should be considered in patients who require alternate access. Since comparative data between different access sites is sparse, an individualized and patient-centric approach in case-to-case basis undertaken by the institutional Heart Team is essential. Transcatheter access can be beneficial as compared with direct aortic and/or transapical approach in patients with advanced lung disease, previous sternotomy, or other thoracic pathology that hampers with subsequent recovery and therefore precludes their use. Transcatheter access can also be technically less intricate when compared with transcatheter approach. Furthermore, as this approach is more widely adapted, long-term results are needed to demonstrate its comparative safety and efficacy.

In conclusion, transcatheter access provides a reasonable alternative access route for TAVI in selected patients. Further comparative data between different vascular access sites and the long-term safety and efficacy data on transcatheter access is essential before this technique is widely adapted.

## Disclosures

The authors report no financial relationships or conflicts of interest regarding the content herein.

## Supplementary materials

Supplementary material associated with this article can be found in the online version at <https://doi.org/10.1016/j.amjcard.2019.09.015>.

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