Meta-Analysis Comparing the Incidence of Infective Endocarditis Following Transcatheter Aortic Valve Implantation Versus Surgical Aortic Valve Replacement

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Infective endocarditis (IE) after transcatheter aortic valve implantation (TAVI) and surgical aortic valve replacement (SAVR) is a rare but life-threatening complication. Paravalvular regurgitation, compression of native leaflets, and space between transcatheter valve prosthesis and native valves could dispose TAVI recipients at increased risk of IE compared with SAVR. To assess the comparative risk of IE between TAVI and SAVR, we performed a systematic review and meta-analysis. A literature search of PUBMED and EMBASE was performed to identify randomized controlled trials that reported the event rate of IE in both TAVI and SAVR. A Mantel-Haenszel method and a random-effects model was used to calculate the odds ratio (OR) and 95% confidence interval (CI). The studied outcomes were early (at 1-year), late (>1-year), and overall IE (post-procedure to longest follow-up) in TAVI versus SAVR. We performed subgroup analysis based on valve-type (self or balloon-expandable) and surgical risk (high or intermediate). A total of 4 studies with 3,761 (1,895 TAVI and 1,866 SAVR) patients were included. The incidence of early IE, (3 studies, 0.86% vs 0.73%, OR 1.17, 95% CI 0.51 to 2.65, p = 0.71, I^2 = 0%), late IE (mean follow-up 2.0 years) (3 studies, 1.3% vs 0.6%, OR 1.85, 95% CI 0.81 to 4.20, p = 0.42, I^2 = 0%), and overall IE (mean follow-up 3.4 years) (4 studies, 2.0% vs 1.3%, OR 1.44, 95% CI 0.85 to 2.43, p = 0.18, I^2 = 0%) was similar between TAVI and SAVR. Subgroup analysis suggested that in intermediate surgical risk cohort, there was a trend toward increased risk of overall IE in TAVI (2.3% in TAVI and 1.2% in SAVR, OR 1.92, 95% CI 0.99 to 3.72, p = 0.05 I^2 = 0%). In this meta-analysis, we did not find an increased risk of IE in TAVI compared with SAVR. Appropriate preventative measure and early recognition of IE in these cohorts are important. **(Am J Cardiol 2019;123:827−832)**

Infective endocarditis (IE) post-transcatheter aortic valve implantation (TAVI) is a complication that remains less investigated owing to its low incidence and challenges in diagnosis. Transcatheter heart valve prosthesis contains a significant amount of metal because of the stent frame housing the leaflets and may have higher risk of IE compared with surgical aortic valve replacement (SAVR) recipients. Paravalvular regurgitation, which occurs more frequently in TAVI, as well as space between the native and transcatheter prosthetic valve could function as a nidus for IE.[1−3] Furthermore, the initial damage of calcific native valve compression from valve insertion and higher incidence of subclinical valve leaflet thrombosis compared with a surgical prosthetic valve[4] may also increase the risk of IE in TAVI. Although staphylococcus species was the leading etiology of IE post-SAVR, enterococcus was the major cause of IE post-TAVI, implicating potentially different entry of pathobiologic mechanisms.[1,5] It is not well investigated whether TAVI have higher risk of IE compared with SAVR. The main aim of this systematic review and meta-analysis was to assess whether the risk of IE in TAVI recipients are higher compared with SAVR patients.

Methods

We searched the PUBMED and EMBASE from January 1st, 2002 to September 26th 2018. We used (TAVI OR TAVR OR transcatheter aortic valve replacement OR transcatheter aortic valve implantation) and (endocarditis OR infectious endocarditis OR infective endocarditis OR randomized OR randomized) as the search term. Two independent authors' (TA and HT) reviewed the search results separately to select the studies based on preset inclusion and exclusion criteria. There was no language restriction. A reference list of included studies for meta-analysis was

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reviewed in an attempt to further minimize missing relevant studies. In an attempt to include the latest data in the rapidly evolving TAVI field, we searched for abstracts in major cardiology conferences (American Heart Association, American College of Cardiology, European Society of Cardiology) for longer-term follow-up data. The study was performed in accordance with the Preferred Reporting Items for Systematic Reviews and Meta-Analyses guideline.[6]

The inclusion criteria were the followings (1) total cohort and event numbers of IE in both TAVI and SAVR group were reported or the study provided risk of IE in TAVI versus SAVR or vice versa in odds ratio/risk ratio/hazard ratio at 1 year or during longer time follow-up period; (2) the study design was randomized controlled trial (RCT) published in peer-review articles or presented at major cardiovascular conferences. (3) The study included at least 100 patients in each arm. The exclusion criteria were (1) case report, review article, or meta-analysis; (2) a single-arm study of either TAVI or SAVR. (3) Follow-up less than 1-year. Two independent authors' (TA and HT) separately extracted the data from selected studies into a spreadsheet. When there was a discrepancy, it was resolved by discussion between these 2 authors'. Cohort and raw event numbers for TAVI and SVAR were extracted at both 1-year follow-up and the longest follow-up available if the outcome of interest was reported. We did not contact the corresponding author for missing information.

Early (≤1 year), late (1 year post-TAVI or SAVR to >1 year longest follow-up), overall (day 0 post-TAVI or SAVR to longest follow-up) incidences of IE from each study in both groups were the outcomes of interest. A subgroup analysis based on valve-type (self or balloon-expandable) and surgical risk (intermediate or high) was planned for overall follow-up IE. The study quality was assessed using the Cochrane risk of bias tool.[7] This was performed by 2 authors (TA and SA).

We used the Review Manager (RevMan) Version 5.3 (Nordic Cochrane Centre, The Cochrane Collaboration, 2012, Copenhagen, Denmark) software in order to calculate the pooled effect size with odds ratio (OR) and 95% confidence intervals (CI) by Mantel-Haenszel method. Heterogeneity was quantitatively expressed by I^2 index and we considered 0% to 25% as low, 26% to 50% as moderate, 51% to 75% as high, and >75% as very high. For each clinical outcome, pooled OR and 95% CI were calculated. In case the percentage of event rate and not the raw number of events was described in the literature, the raw event number was calculated from the total cohort and the described percentage of the event rate. The intention to treat cohort and event numbers/rates were used whenever available and in the case when the outcomes of intention treat to treat analysis was not reported, the as-treated cohort and event numbers/rates were used to calculate OR and 95% CI. Two types of sensitivity analyses were performed for every outcome except for subgroup analysis. First, both random-effects and fixed effect model was used. Second, each study was removed once at a time and the pooled effect size was recalculated each time. Publication bias was assessed when more than 10 studies were included in the meta-analysis with Egger's test. A p value of less than 0.05 was considered significant.

Results

We identified 4 RCTs and 7 manuscripts that fulfilled our criteria.[3,8–13] The main summary of included studies is summarized in Table 1. The definition of IE differed across studies as summarized in Table 1. The flow chart of study selection is available in Figure 1.

A total of 3,011 patients (1,504 TAVI and 1,507 SAVR) were included to calculate early IE from 3 studies. The incidence of IE was 0.86% in TAVI and 0.73% in SAVR and was similar (OR 1.17, 95% CI 0.51 to 2.65, $p = 0.71$, $I^2 = 0\%$; Figure 2) at 1-year follow-up.

The incidence of late IE form a total of 3 studies from 3,011 (1,504 TAVI and 1,507 SAVR) patients during a mean follow up of 2.0 years were 1.3% and 0.6% (OR 1.85, 95% CI 0.81 to 4.20, $p = 0.14$, $I^2 = 0\%$; Figure 3), respectively.

From 4 studies, a total of 3,761 (1,895 TAVI and 1,866 SAVR) patients were analyzed for the incidence of overall IE during a mean of 3.4-years of follow-up. IE occurred in 2.0% in TAVI and 1.3% in SAVR. There was no difference in the risk of overall IE between TAVI and SAVR (OR 1.44, 95% CI 0.85 to 2.43, $p = 0.18$, $I^2 = 0\%$; Figure 4).

Exploratory subgroup analysis based on valve type or surgical risk was performed for overall IE. Both self-expandable (3.9% in TAVI and 2.6% in SAVR, OR 1.53, 95% CI 0.74 to 3.14, $p = 0.25$, $I^2 = 0\%$) and balloon-expandable (1.2% in TAVI and 0.9% in SAVR, OR 1.34, 95% CI 0.62 to 2.89, $p = 0.46$, $I^2 = 1\%$) valves did not differ in the incidence of overall IE. When divided according to surgical risk, high surgical risk showed a similar incidence of IE (1.4% in TAVI and 1.5% in SAVR, OR 0.88, 95% CI 0.37 to 2.08, $p = 0.76$). TAVI showed a tendency toward increased risk (2.3% in TAVI and 1.2% in SAVR, OR 1.92, 95%CI 0.99 to 3.72, $p = 0.05$, $I^2 = 0\%$) of overall IE in intermediate surgical risk cohort in TAVI compared with SAVR during the follow-up. Publication bias was not evaluated for each outcome as less than 10 studies were included. Quality of the studies included in this meta-analysis is summarized in supplement 1. In all outcomes, sensitivity analyses showed consistent results and there was no significant heterogeneity.

Discussion

Despite several potential mechanisms raising concerns of TAVI being at increased risk of IE compared with SAVR, our analysis showed similar incidence of IE between TAVI and SAVR. Previous studies reported the incidence of non-TAVI prosthetic IE to be 0.3% to 1% per person-year.[14–16] A previous retrospective single-center cohort of 180 patients reported a post-TAVI IE incidence of as high as 3.4% per patient-year.[17] However, in line with our findings, International registry of IE post-TAVI reported the incidence to be 1.1% per person-year.[1] IE post-TAVI may be underdiagnosed because of the diagnosis challenges involved. TAVI patients are usually older with multiple co-morbidities and the clinical presentation could be very atypical.[18] In addition, the Duke criteria have low sensitivity in the diagnosis of prosthetic heart valve IE.[19,20] In a case series of 16 patients referred suspicious

Table 1
Summary of included studies

Author/initial publication, year	PARTNER[8,9]		US CoreValve[10,11]		NOTION[12,13]		PARTNER 2[3]	
Study design	Randomized controlled trial		Randomized controlled, noninferiority trial		Investigator-initiated, randomized, nonblinded, superiority trial		Two parallel prospective, randomized controlled trial	
Study period	May 2007-August 2009		February 2011-September 2012		December 2009-April 2013		December 2011-November 2013	
Follow-up duration	5 years		5 years		5 years		2 years	
Used valves	SAPIEN heart-valve system (Edwards Life-sciences)		Core-Valve self-expanding prosthesis (Medtronic)		Core-Valve self-expanding prosthesis (Medtronic)		Sapien XT valve system (Edwards Life-sciences)	
Procedure	TAVI	SAVR	TAVI	SAVR	TAVI	SAVR	TAVI	SAVR
Cohort number	348	351	390	357	145	135	1,011	1,021
Age, years	83.6 ± 6.8	84.5 ± 6.4	83.1 ± 7.1	83.2 ± 6.4	79.2 ± 4.9	79.0 ± 4.7	81.5 ± 6.7	81.7 ± 6.7
Male sex	57.8%	56.7%	53.1%	52.4%	53.8%	52.6%	54.2%	54.8%
STS score	11.8 ± 3.3	11.7 ± 3.5	7.3 ± 3.0	7.5 ± 3.4	2.9 ± 1.6	3.1 ± 1.7	5.8 ± 2.1	5.8 ± 1.9
EuroScore	29.3 ± 16.5	29.2 ± 15.6	17.7 ± 13.1	18.6 ± 13.0	8.4 ± 4.0	8.9 ± 5.5	NR	NR
COPD	43.4%	43.0%	NR	NR	11.7%	11.9%	31.8%	30.0%
Renal failure	†11.1%	†7.0%	‡12.2%	‡12.8%	†1.4%	†0.7%	5.0%	5.2%
Previous MI	26.8%	30.0%	25.4%	25.2%	5.5%	4.4%	18.3%	17.5%
Previous CABG	42.6%	44.2%	29.5%	31.1%	NR	NR	23.6%	25.6%
Frail	15.6%	17.6%	NR	NR	NR	NR	*15.2%	*14.7%
Trans-apical approach	29.9%	-	17.2%	-	0	-	§23.3%	-
Study support	Edwards lifesciences		Medtronic		The Danish Heart Foundation Statistical support by Medtronic		Edwards lifesciences	

CABG = coronary artery bypass graft; COPD = chronic obstructive pulmonary disease; MI = myocardial infarction; NOTION = nordic aortic valve intervention; NR = not reported; PARTNER = placement of aortic transcatheter valve; SAVR = surgical aortic valve replacement; STS = Society of Thoracic Surgeon; TAVI = transcatheter aortic valve implantation.

* Serum albumin <3.5 g/dl.

† Creatinine level >2 mg/dl.

‡ Chronic kidney disease stage 4 or 5.

§ Transthoracic access.

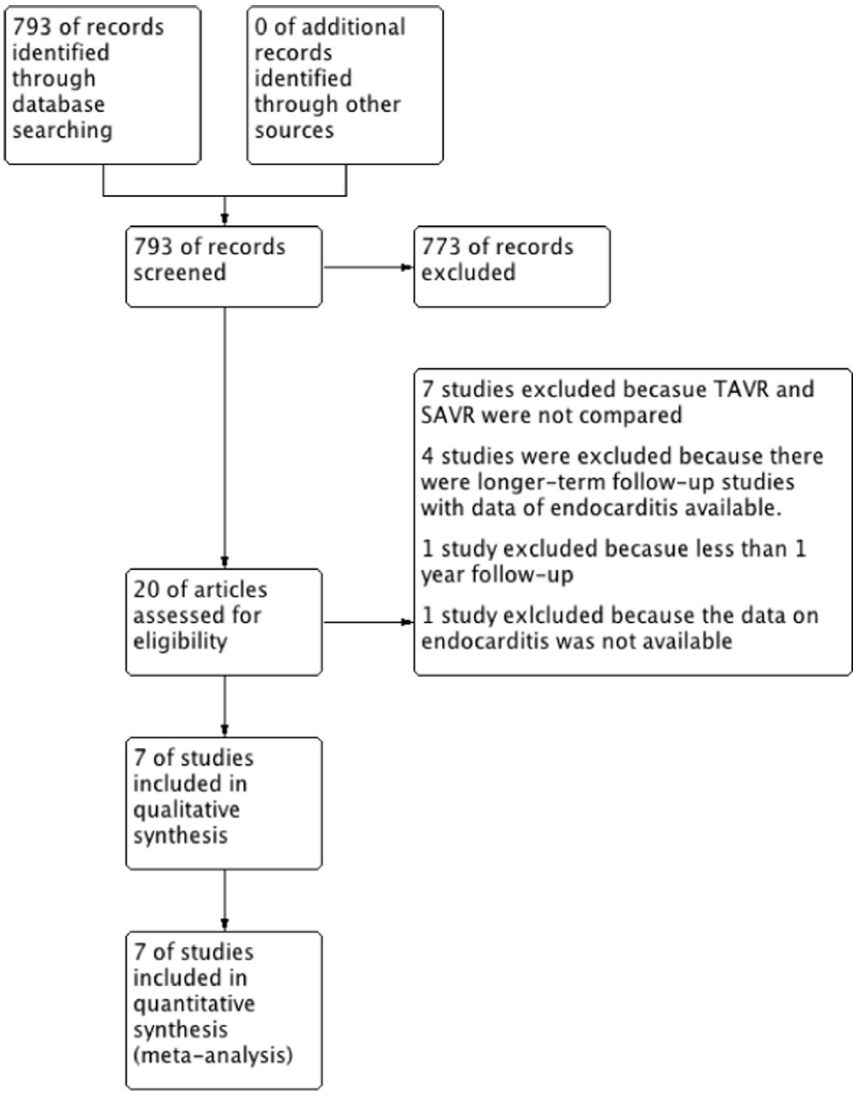

Figure 1. Study selection flow.

for IE post-TAVI, multimodality imaging had a higher diagnostic value compared with modified Duke criteria.[20] Adjunctive use of ^{18}F-fluorodeoxyglucose positron-emission tomography can increase the sensitivity and specificity of the diagnosis.[21] These new concepts and technologies should be considered in challenging cases. A previous study suggested nosocomial infection to be significantly associated with the development of prosthetic IE. However, a prospective single-center study examined the infectious complications in TAVI and SAVR did not suggest significant differences in infections and that could partially explain why the incidence of IE was similar in the 2 groups in this meta-analysis.[22]

One of the interesting findings of our analysis is that the subgroup analysis of intermediate surgical risk patients showed a trend toward higher risk of IE in the TAVI group. Since we only included 2 studies, this should be considered only hypothesis generating or possibly a chance association.

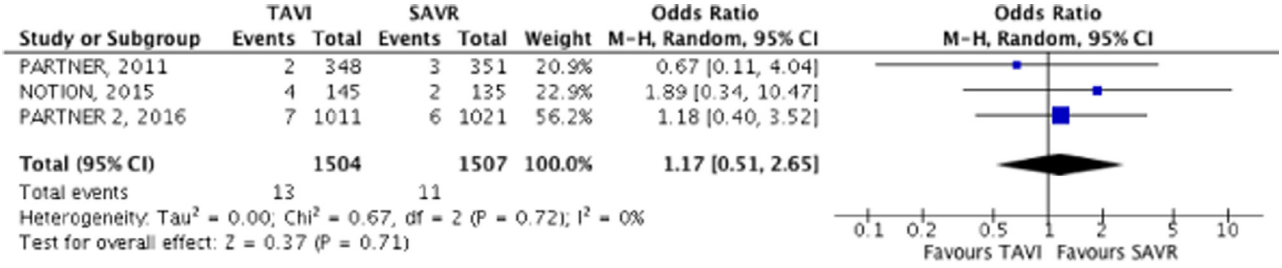

Figure 2. Forest plot of early endocarditis TAVI versus SAVR.
SAVR = surgical aortic; TAVI = transcatheter aortic valve implantation.

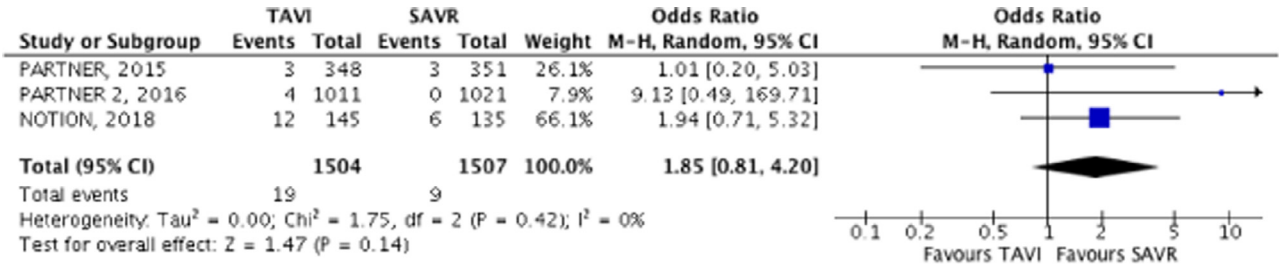

Figure 3. Forest plot of late endocarditis TAVI versus SAVR.
SAVR = surgical aortic valve replacement; TAVI = transcatheter aortic valve implantation.

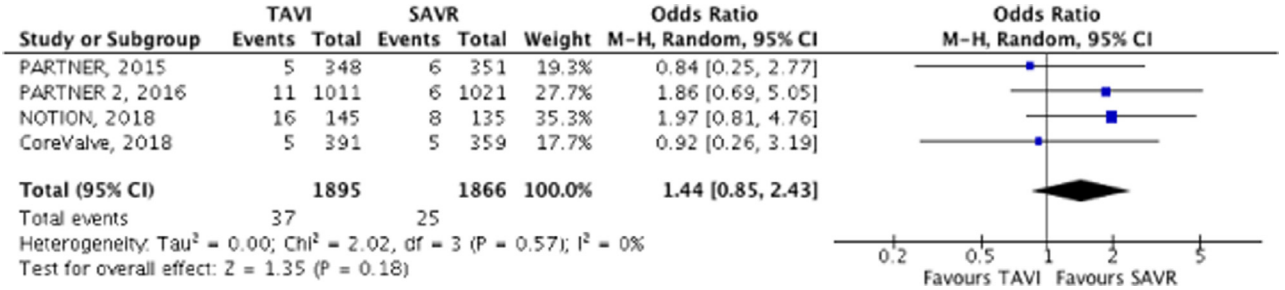

Figure 4. Forest plot of overall endocarditis TAVI versus SAVR.
SAVR = surgical aortic valve replacement; TAVI = transcatheter aortic valve implantation.

Based on the Infectious Endocarditis after TAVI International Registry which identified 250 cases of infective endocarditis in 20,006 patients after TAVI, younger age, diabetes, more than moderate aortic regurgitation, and male gender were associated with increased risk of IE.[1] Although direct comparison is not feasible, the mean age, percentage of men, diabetes, and more than moderate aortic regurgitation of NOTION and PARTNER 2 appears to be comparable to the PARTNER and the US CoreValve study. Further follow-up using latest iteration of valves could shed further light on this matter.

There are several limitations. First, this was a study-level and not patient-level meta-analysis. Therefore may have allowed more bias in the results. However, included studies were all RCTs. Second, we were only able to include 4 studies in the meta-analysis and this could have limited the statistical power. Especially, subgroup analysis only included 2 studies and should be considered hypothesis-generating. Third, the most recent RCT, Surgical or Transcatheter Aortic-Valve Replacement trial[23] in intermediate risk patients did not report the data on IE and therefore had to be excluded from the analysis. Fourth, we were unable to report microbiology of IE in each group. Fifth, the definition of IE was not consistent among studies and could have resulted in different incidence. Last, it was not reported whether IE was "definite" or "possible" IE in each study.

Disclosures

All investigators have no disclosures.

Supplementary materials

Supplementary material associated with this article can be found, in the online version, at doi:10.1016/j.amjcard.2018.11.031.

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