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A Meta-Analysis of Transfemoral versus Transapical Transcatheter Aortic Valve Implantation on 30-Day and 1-Year Outcomes

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ABSTRACT

Background: Transfemoral (TF) and transapical (TA) are two commonly used accesses in transcatheter aortic valve implantation (TAVI). Currently, the influence of TAVI access choice on 30-day and 1-year outcomes is unclear. The purpose of this study was to compare the 30-day and 1-year outcomes between TF-TAVI and TA-TAVI.

Methods: Studies published from 2002 to September 2014 were collected by searching PubMed and Web of Knowledge. Studies were selected by two independent investigators. 30-day and 1-year outcomes were endpoints. Odds ratios (ORs) and hazard ratio (HR) with 95% confidence interval (CI) were computed. Fixed effect model was used if $I^2 < 50\%$; if $I^2 > 50\%$, random effect model was used.

Results: 14 studies met inclusion criteria and were included in our analysis (3837 patients in TF group, 1881 patients in TA group). Two were retrospective trials and the others were prospective trials. Our meta-analysis showed that compared with TA group, TF group had a lower 30-day mortality (7.5% versus 11.6%) and higher 1-year survival [HR 0.75, 95% CI (0.66, 0.86)], but the Logistic EuroSCORE was higher in TA group ($P = 0.00$). TF group had a significantly higher stroke rate of 4.0% compared with 2.2% in TA group at ≤30 days. The incidence of major vascular complications was significantly higher in TF group compared with TA group (8.2% versus 5.3%). MI was more common in TA group (2.4%) compared with TF group (1.2%), but there were no significant difference [0.46, 95% CI (0.20, 1.06)].

Conclusions: TF-TAVI had a higher 30-day and 1-year survival rate compared with TA-TAVI, but these differences might be because of the higher Logistic EuroSCORE in TA group. Stroke and major vascular complications rates were higher in TF-TAVI patients at ≤30 days.

INTRODUCTION

Transcatheter aortic valve implantation (TAVI) is a novel treatment for patients with severe aortic stenosis (AS) who are aged and cannot tolerate conventional surgical aortic valve replacement (SAVR). In a recent meta-analysis, TAVI was compared with SAVR and was demonstrated to be a better choice for high-risk patients with AS [Takagi 2013].

The approaches of TAVI include transfemoral (TF), transapical (TA), transaortic, transcarotid and subclavian, the most commonly used being TF and TA. TF is a retrograde approach and TA is an anterograde approach with a minithoracotomy in the left ventricular apical. A previous meta-analysis of 20 studies showed TF has a low incidence of 30-day mortality compared with TA procedure [Li 2013], but little is known about TF versus TA on midterm outcome. The main objective of this meta-analysis was to compare not only the early but also the midterm outcomes between TF- and TA-TAVI.

MATERIALS AND METHODS

We conducted this meta-analysis following the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) [Moher 2009] and Meta-Analysis of Observational Studies in Epidemiology (MOOSE) [Stroup 2000].

Search Strategy

We identified studies published from 2002 to September 2014 through searching PubMed and Web of Knowledge using the follow terms: TAVI, transcatheter aortic valve implantation, TAVR, transcatheter aortic valve replacement,

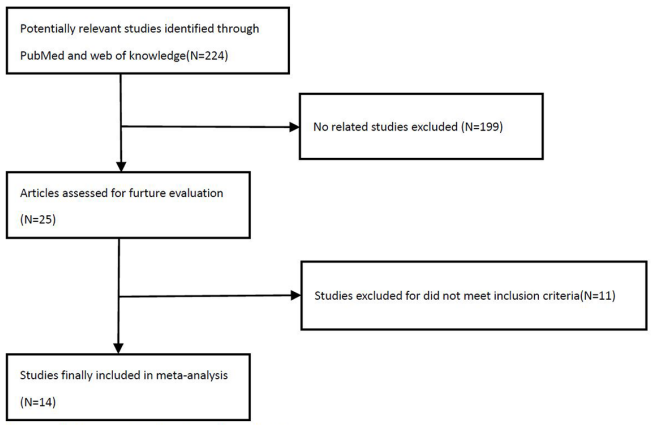

Figure 1. Process for final study selection.

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Characteristics of Included Studies

Study	Year	0.0556 in			Logistic EuroSCORE (%)*		STS SCORE (%)*		30-day outcomes								1-year outcomes
									Mortality		Stroke		Myocardial infarction		Major vascular complication		
		TF	TA	Total	TF	TA	TF	TA	TF	TA	TF	TA	TF	TA	TF	TA	TF versus TA
HR (95% CI)																	
Himbert et al	2009	51	24	75	25 ± 13	28 ± 13	15 ± 7	18 ± 9	4	2	3	0	3	1	6	2	0.52 (0.15-1.80)
Webb et al	2009	113	55	168	–	–	–	–	9	10	6	1	–	–	9	2	1.85 (0.99-3.43)
Dworakowski et al	2010	67	84	151	19.4 ± 1.1	23.4 ± 1.5	–	–	4	11	5	4	–	–	11	2	0.59 (0.25-1.39)
Rodes-Cabau et al	2010	162	177	339	–	–	9.0 ± 5.8	10.5 ± 6.9	16	20	5	3	1	3	–	–	0.90 (0.57-1.42)
Ewe et al	2011	45	59	104	20.1 ± 11.7	22.6 ± 11.9	8.5 ± 3.8	8.9 ± 3.5	2	3	2	2	0	1	7	16	1.49 (0.48-4.62)
Johansson et al	2011	10	30	40	–	–	25.6 ± 15	23.5 ± 17	1	2	2	1	–	–	–	–	2.86 (0.47-17.27)
Lefevre et al	2011	61	69	130	25.7 ± 11.5	33.8 ± 14.4	11.3 ± 6.1	11.8 ± 6.8	5	13	2	1	2	4	17	3	0.40 (0.19-0.86)
Puls et al	2012	83	97	180	–	–	–	–	4	12	5	4	0	3	50	44	0.61 (0.30-1.21)
Schymik et al	2012	174	126	300	21.9 ± 15.9	27.0 ± 18.0	–	–	13	5	–	–	–	–	–	–	1.22 (0.66-2.23)
Gilard et al	2012	2361	567	2928	21.2 ± 14.7	24.8 ± 14.7	14.5 ± 11.9	15.1 ± 13.8	190	77	–	–	–	–	–	–	0.68 (0.55-0.83)
Hemmann et al	2013	274	152	426	19.5 ± 14.2	24.2 ± 14.9	–	–	13	19	–	–	–	–	–	–	0.62 (0.38-1.02)
Griese et al	2013	179	212	391	17.4 ± 12.5	23.4 ± 15.2	–	–	6	15	1	3	1	1	1	1	0.70 (0.44-1.10)
Walters et al	2014	67	62	129	–	–	–	–	4	6	2	3	1	4	10	3	0.61 (0.17-2.09)
Lotfi et al	2014	190	167	357	22.16 ± 13.05	31.04 ± 16.40	–	–	16	19	8	1	–	–	39	3	0.82 (0.50-1.32)

*Data are presented as the mean ± SD. TF indicates transfemoral; TA, transapical; STS, Society of Thoracic Surgeons; HR, hazard ratio.

transapical and transfemoral. Abstract presentations at congresses were also reviewed to identify other studies.

Selection Criteria

Search results were reviewed by two independent investigators (AZ, HM) at the title or abstract level and then complete articles of studies that had potential according to inclusion criteria were found and assessed. The studies finally included in this meta-analysis met the following criteria: (a) Study design and end point must be clearly described in study; (b) Study was designed to compare outcomes between TF- and TA-TAVI; (c) Patients' baseline characteristics should be provided; (d) 30-day and 1-year outcomes must be described in study.

Data Extraction

The following information from each study was extracted by two independent reviewers (AZ, HM): authors, publication time, study design, study size, inclusion and exclusion criteria, patients' baseline characteristics, major adverse outcomes, 30-day and 1-year outcomes. All-cause mortality at 1-year was the primary end point.

Data Analysis

Odds ratio (OR) and hazard ratio (HR) with the corresponding 95% confidence interval (CI) were respectively used to assess 30-day and 1-year outcome difference between TF- and TA-TAVI. If the study did not provide 1-year HR of TF

versus TA groups, it was extracted from Kaplan-Meier curve according to the recommendations of Tierney et al [Tierney 2007]. We chose HR as 1-year effect size in our meta-analysis because compared with OR, HR is superior to describe time-to-event outcomes. I-squared test was used to assess the heterogeneity assumption. Fixed effect model was used if $I^2 < 50\%$ and if $I^2 > 50\%$, random effect model was used. Student t test was used for the analysis of continuous variables.

Stata Version 13.1 (College Station, TX, USA) was used to perform data analysis. Graphical inspection of funnel plots was used to assess publication bias. All data was presented as mean ± SD. Two-tailed *P* values of .05 or less were considered to be statistically significant.

RESULTS

Baseline Features of Final Selected Studies

The retrieval process is shown in Figure 1. Finally, 14 studies met inclusion criterias and were included for our analysis [Himbert 2009; Webb 2009; Dworakowski 2010; Ewe 2011; Johansson 2011; Lefevre 2011; Puls 2012; Schymik 2012; Rodes-Cabau 2010; Gilard 2012; Hemmann 2013; Griese 2013; Walters 2014; Lotfi 2014]. Among them, two were retrospective trials and the others were prospective trials. Our meta-analysis included 3837 patients in TF group and 1881 patients in TA group. The extracted data of included studies is shown in the Table. Logistic EuroSCORE was provided by 9 studies which include 3402 TF patients and 1460 TA patients [Himbert 2009; Dworakowski 2010; Ewe 2011; Lefevre 2011; Schymik 2012; Gilard 2012; Hemmann 2013; Griese 2013; Lotfi 2014]. The merged Logistic EuroSCORE was 21.0 ± 14.3% in TF group compared with 25.7 ± 15.0% in TA group; the difference reached statistical significance (*P* = 0.00). STS SCORE was provided by 6 studies which included 2190 TF patients and 926 TA patients [Himbert 2009; Ewe 2011; Johansson 2011; Lefevre 2011; Rodes-Cabau 2010; Gilard 2012]. The merged STS SCORE was 14.0 ± 11.5% in TF group compared with 13.9 ± 12.2% in TA group; there was no significant different (*P* = .60).

30-Day Outcomes

All 14 studies reported 30-day postoperative mortality [Himbert 2009; Webb 2009; Dworakowski 2010; Ewe 2011; Johansson 2011; Lefevre 2011; Puls 2012; Schymik 2012; Rodes-Cabau 2010; Gilard 2012; Hemmann 2013; Griese 2013; Walters 2014; Lotfi 2014]. As shown in Figure 2, our meta-analysis of the data showed a difference between the TF-TAVI and TA-TAVI groups in pooled 30-day mortality [7.5% (287/3837) versus 11.6% (214/1848)] and this difference reached statistical significance [0.57, 95% CI (0.47, 0.70)].

30-day postoperative stroke rate was reported in 11 studies [Himbert 2009; Webb 2009; Dworakowski 2010; Ewe 2011; Johansson 2011; Lefevre 2011; Puls 2012; Rodes-Cabau 2010; Griese 2013; Walters 2014; Lotfi 2014]. As shown in Figure 3, our meta-analysis showed the pooled 30-day stroke rate in TF group was 4.0% (41/1028), compared with 2.2% (23/1036) in TA group and the difference reached statistical significance [1.85, 95% CI (1.10, 3.13)].

7 studies reported 30-day postoperative myocardial infarction (MI) [Himbert 2009; Ewe 2011; Lefevre 2011; Puls 2012; Rodes-Cabau 2010; Griese 2013; Walters 2014]. The pooled 30-day postoperative MI rate was 1.2% (8/648) in TF group and 2.4% (17/700) in TA group, but the difference between TF and TA groups had no significant difference [0.46, 95% CI (0.20, 1.06)], as shown in Figure 4.

8 studies reported 30-day postoperative major vascular complication [Himbert 2009; Webb 2009; Dworakowski 2010; Ewe 2011; Lefevre 2011; Puls 2012; Griese 2013; Walters 2014]. Data were extracted from those 8 studies and meta-analysis of these data showed the pooled 30-day postoperative major vascular complication was 8.2% (54/656) in TF group and 5.3% (35/662) in TA group. 30-day postoperative major vascular complication between the TF and TA groups were significantly different [1.64, 95% CI (1.03, 2.60)], as shown in Figure 4.

1-Year Outcome

14 studies all provided postoperative 1-year outcomes [Himbert 2009; Webb 2009; Dworakowski 2010; Ewe 2011;

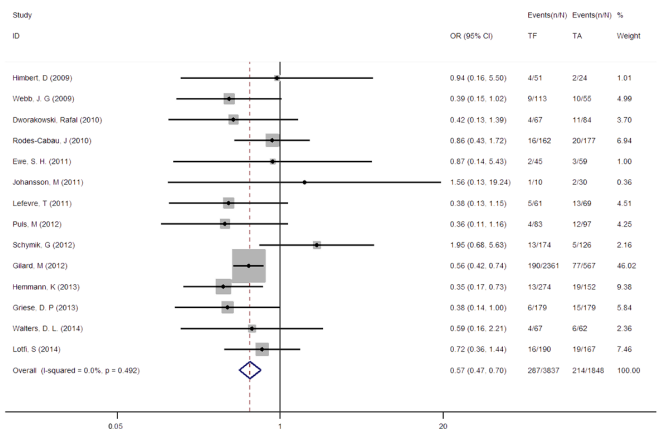

Figure 2. Meta-analysis comparison of 30-day postoperative mortality for transfemoral transcatheter aortic valve implantation versus transapical transcatheter aortic valve implantation.

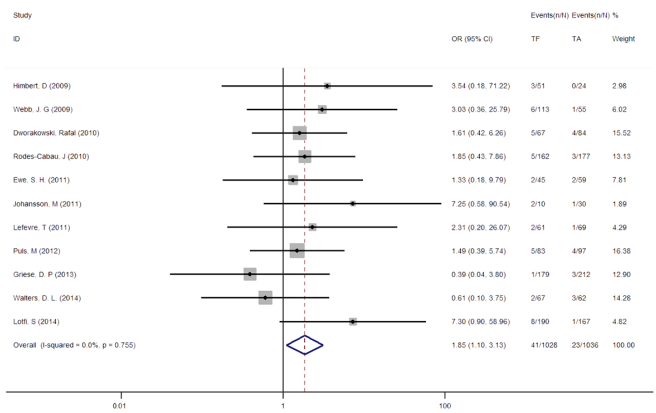

Figure 3. Meta-analysis comparison of 30-day postoperative stroke rate for transfemoral transcatheter aortic valve implantation versus transapical transcatheter aortic valve implantation.

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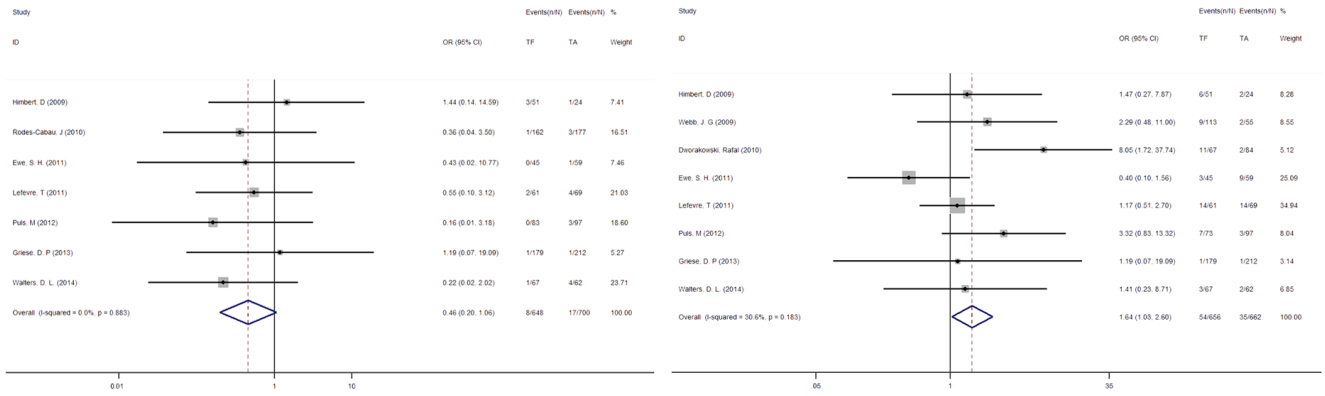

Figure 4. Meta-analysis comparison of 30-day postoperative myocardial infarction rate (right) and 30-day postoperative major vascular complication rate (left) for transfemoral transcatheter aortic valve implantation versus transapical transcatheter aortic valve implantation.

Johansson 2011; Lefevre 2011; Puls 2012; Schymik 2012; Rodes-Cabau 2010; Gilard 2012; Hemmann 2013; Griese 2013; Walters 2014; Lotfi 2014]. As shown in Figure 5, our meta-analysis showed TF-TAVI was superior to TA-TAVI with a pooled HR of 0.75 [95% CI (0.66, 0.86)], which indicated that compared with TA-TAVI, TF-TAVI provided a better survival rate in a year time.

Sensitivity and Publication Bias Analysis

First, two retrospective studies were excluded to inspect whether study design could influence the final result. Then, studies with large OR or HR were excluded and most pooled estimates were similar to the final result. Our sensitivity analysis indicated that the results are robust. Graphical inspection of funnel plots was used to assess publication bias. The funnel plot for 30-day postoperative mortality and 1-year mortality are respectively shown in Figure 6. Begg's test for 30-day postoperative mortality (P = .324) and 1-year mortality (P = .584) did not reveal any publication bias.

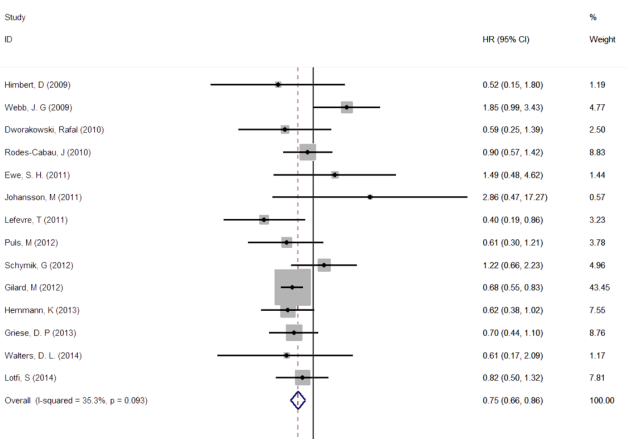

Figure 5. Meta-analysis comparison of 1-year postoperative survival rate for transfemoral transcatheter aortic valve implantation versus transapical transcatheter aortic valve implantation.

DISCUSSION

Alan Cribier et al [Cribier 2002] performed the first human TAVI in 2002, and TAVI is now widely used in high-risk elderly patients with symptomatic severe AS. Through the meta-analysis of 14 studies including 5718 patients, the main purpose of this meta-analysis is to present a reliable assessment of TF versus TA approach on TAVI outcomes.

The contrast between the TF and TA group in our meta-analysis identified that compared with transapical patients, transfemoral patients had a lower 30-day mortality (7.5% versus 11.6%) and a protective effect on 1-year survival [HR 0.75, 95% CI (0.66, 0.86)]. The specific reason for this result is unclear, but selection bias favoring TF approach and different patient characteristics may play a role. Although TA-TAVI has a short delivery distance that can get a more accurate valve position, it needs a minithoracotomy in the left ventricular apical, which makes it more invasive than TF-TAVI. Currently, the access choice is based on clinical characteristics in most studies and TF-TAVI is inclined to be chosen in most low-risk patients. We found the Logistic EuroSCORE was higher in TA group than TF group; this may partially explain its poor postoperative survival compared with TA group. Logistic EuroSCORE or STS SCORE may be helpful for access choice of TAVI, but those two scoring system were developed based on surgical patients and may not be appropriate to assess TAVI patients. Some studies report that there are no differences in 1-year survival between TF and TA groups [Puls 2012]. But our study showed that TF group also had a lower 1-year mortality compared with TA group. This may in part be because of the higher Logistic EuroSCORE in TA group. The exact reason for these differences between TF and TA groups remains to be clarified by more randomized clinical trials.

TF group had a significantly higher stroke rate of 4.0% compared with 2.2% in TA group at ≤30 days. Earlier studies reported that there were no differences in stroke rates between the TF and TA groups [Li 2013]. Our result was in accord with the previous study, which reported the stroke rate for TF-TAVI was higher than for TA-TAVI because of

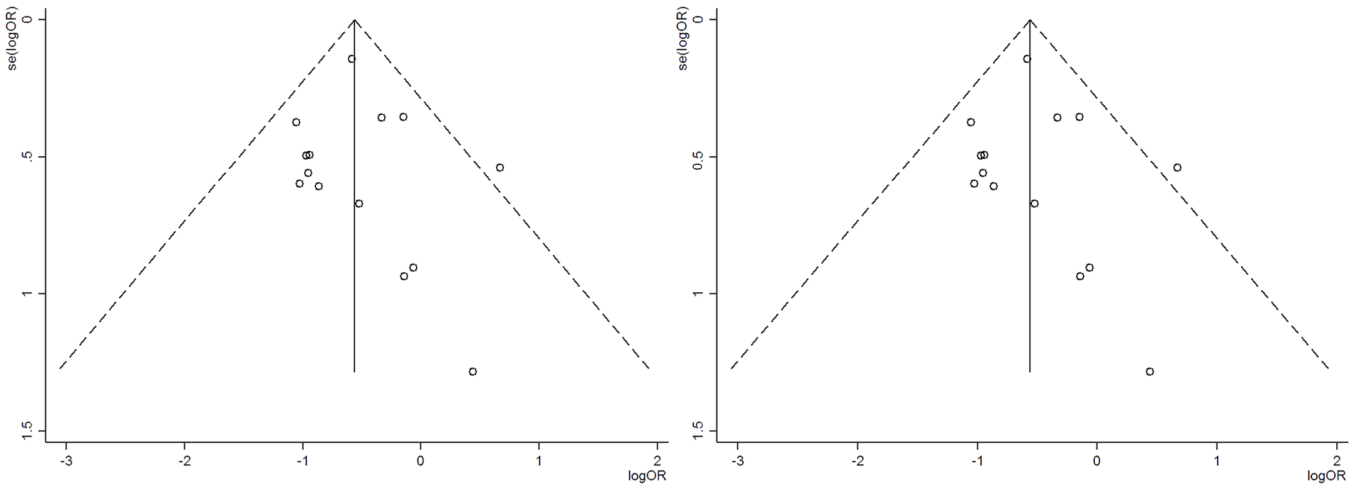

Figure 6. Funnel plot for 30-day postoperative mortality (left) and 1-year postoperative mortality (right).

the passage of the 22F or 24F sheath around the aortic arch [Webb 2009]. Empiric dual-oral antiplatelet therapy and long-term daily low-dose aspirin were recommended and may reduce the stroke rate. TAVI-device reformation can also reduce the stroke rate; it was reported that stroke was completely prevented by using the new embolic deflection device during TF- and TA-TAVI [Masson 2009].

MI was more common in TA group (2.4%) compared with TF group (1.2%). But our study showed there were no significant differences [0.46, 95% CI (0.20, 1.06)]. This may be related to careful patient selection, device preparation, optimal device progression, and positioning. Different learning curves of those two methods may also play a role in this result. Although there were no significant differences between TA and TF groups at ≤30 days in our study, Giordana et al [Giordana 2014] reported MI was a predictor of midterm mortality.

Van der Boon et al [van der Boon 2014] reported TA group had fewer major vascular complications in comparison with TF group. Our study also showed the incidence of major vascular complications was significantly higher in TF group compared with TA group (8.2% versus 5.3%). But major vascular complications were more life-threatening in TA-TAVI; it was reported that bleeding was an independent predictor of midterm mortality [Borz 2013]. A previous study showed that there were no differences in bleeding complication between TF and TA groups [Ewe 2011]. Major vascular complications of TAVI may decrease with the use of smaller delivery catheters and the innovation of TAVI technology [Van Mieghem 2013].

Our study had several limitations. Cardiac mortality might be a more appropriate effect size to assess the midterm difference between the two groups, but most studies only provided all-cause mortality. No randomized controlled trial was included in our study and the baseline characteristics might be different between TF and TA groups. Our meta-analysis only brought in studies published in English-language journals and publication bias might have occurred.

Through our meta-analysis, we found TF group had a higher 30-day and 1-year survival rate compared with TA group, but these differences might be because of the higher Logistic EuroSCORE in TA group. Stroke and major vascular complication rates were higher in TF group at ≤30 days. The influence of TAVI access on outcome requires more randomized controlled trials to evaluate.

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