Clinical Kidney Journal, 2016, vol. 9, no. 4, 560–566

doi: 10.1093/ckj/sfw055
Advance Access Publication Date: 19 June 2016
Original Article

ORIGINAL ARTICLE

The risk of acute kidney injury following transapical versus transfemoral transcatheter aortic valve replacement: a systematic review and meta-analysis

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Abstract

Background: The aim of this systematic review is to examine the literature for the risk of acute kidney injury (AKI) in patients who underwent transcatheter aortic valve replacement (TAVR) based on transapical (TA) versus transfemoral (TF) approaches.

Methods: A literature search was conducted utilizing Embase, Medline, Cochrane Database of Systematic Reviews and ClinicalTrials.gov from inception through December 2015. Studies that reported relative risk, odds ratio or hazard ratio comparing the AKI risk in patients who underwent TA-TAVR versus TF-TAVR were included. Pooled risk ratio (RR) and 95% confidence interval (CI) were calculated using a random effect, generic inverse variance method.

Results: Seventeen cohort studies with 5085 patients were enrolled in the analysis to assess the risk of AKI in patients undergoing TA-TAVR versus TF-TAVR. The pooled RR of AKI in patients who underwent TA-TAVR was 2.26 (95% CI 1.79–2.86) when compared with TF-TAVR. When meta-analysis was confined to the studies with adjusted analysis for confounders evaluating the risk of AKI following TAVR, the pooled RR of TA-TAVR was 2.89 (95% CI 2.12–3.94). The risk for moderate to severe AKI [RR 1.02 (95% CI 0.57–1.80)] in patients who underwent TA-TAVR compared with TF-TAVR was not significantly higher.

Conclusions: Our meta-analysis demonstrates an association between TA-TAVR and a higher risk of AKI. Future studies are required to assess the risks of moderate to severe AKI and mortality following TA-TAVR versus TF-TAVR.

Key words: acute kidney injury, meta-analysis, transapical, transfemoral, transcatheter aortic valve replacement, mortality

Introduction

Transcatheter aortic valve replacement (TAVR), also known as transcatheter aortic valve implantation (TAVI), has now emerged as a viable treatment option for high-risk patients with severe aortic stenosis who are not suitable candidates for aortic valve replacement [1–5]. To date, >200 000 procedures have been performed worldwide [6]. Despite encouraging reports, AKI remains a common complication of TAVR, ranging from 15 to 57% [2, 7–9].

Received: February 7, 2016. **Accepted:** April 13, 2016

Transfemoral (TF) and transapical (TA) are the two most common approaches for TAVR procedures. TF-TAVR is considered the first choice at most centers, as it can be performed using moderate sedation and local anesthetics and also has shorter procedural and recovery times [8, 10–12]. The patients who underwent TA-TAVR usually had more comorbid conditions, in particular, peripheral vascular disease, which is a known risk factor for AKI following TAVR [6, 13]. On the other hand, compared with TA-TAVR, TF-TAVR generally requires a higher volume of contrast agent and a well-established cause for contrast-induced AKI. It is, therefore, not surprising that studies evaluating the risk of AKI in patients following TA-TAVR versus TF-TAVR are conflicting. A few studies have demonstrated higher AKI risk among symptomatic AS patients who underwent TA-TAVR [13–20]. Conversely, several studies have found no significantly greater incidence of AKI in patients who underwent TA-TAVR [21–28].

Thus, this systematic review and meta-analysis was conducted to compare the effects of TA-TAVR and TF-TAVR on the risk of AKI.

Materials and methods

Search strategy

Two investigators (C.T. and W.C.) independently searched published studies and conference abstracts indexed in Embase, Medline, Cochrane Database of Systematic Reviews and ClinicalTrials.gov from inception of the databases through December 2015 using the search strategy described in Supplementary data, Item S1. We also performed a manual search for additional relevant studies using the references from these retrieved articles.

Inclusion criteria

The inclusion criteria for this meta-analysis were (i) randomized controlled trials (RCTs) or observational studies published as original articles or conference abstracts that assessed the risk of AKI in patients who underwent TA-TAVR, (ii) available data on relative risk, odds ratio or hazard ratio with 95% confidence intervals (CIs) and (iii) a reference group comprising subjects who underwent TF-TAVR. No limits were implemented for language.

Study eligibility was individually determined by the two investigators noted as above. Differing decisions were solved by joint consensus. We appraised the quality of each included study by utilizing the Jadad quality assessment scale [29] for RCTs and the Newcastle–Ottawa quality assessment scale [30] for observational studies.

Data extraction

A standardized data collection form was used to extract the following information: last name of the first author, the title of the article, study design, year of study, country of origin, year of publication, sample size, AKI definition, mortality, confounder adjustment and adjusted effect estimate with 95% CI.

Statistical analysis

We performed data analysis using Review Manager software from the Cochrane Collaboration (Version 5.3, Copenhagen, Denmark). Point estimates and standard errors were obtained from each of the included studies and were united by the generic inverse variance method [31]. Given the high likelihood of between-study variances, a random effects model was used. Statistical heterogeneity was evaluated utilizing Cochran's Q test. The I^2 statistic was computed to estimate the degree of variation across studies related to heterogeneity instead of chance. An I^2 of 0–25% renders insignificant heterogeneity, 26–50% low heterogeneity, 51–75% moderate heterogeneity and >75% high heterogeneity [32]. The presence of publication bias was appraised by funnel plots of the logarithm of odds ratios versus their standard errors [33].

Results

Our search strategy yielded 1327 relevant articles. Of these, 1169 were excluded based on the following measures: the abstract failing to indicate an appropriate type of article, study design, population or outcome of interest. The remaining 158 articles underwent full-length review and 141 of these were excluded for failing to meet criteria (113 articles did not report the outcomes of interest and 28 articles were not observational studies or RCTs). Seventeen cohort studies [13–28, 34] with 5085 patients were included in the meta-analysis to assess the risk of AKI in patients undergoing TA-TAVR versus TF-TAVR (Table 1).

Of the 17 cohort studies, 8 performed adjusted analysis for known risk factors for AKI [14–16, 18–21, 34]. Only four cohort studies assessed the risk of moderate to severe AKI in patients undergoing TA-TAVR versus TF-TAVR [17, 19, 20, 27]. Within selected studies, five were included in the post hoc analysis assessing mortality outcomes [17, 19, 20, 23, 27]. Supplementary data, Item S2 outlines our search methodology and selection process.

AKI definition

All included studies identified the AKI occurrence, based on the change in serum creatinine (SCr) or glomerular filtration rate (GFR) after TAVR. These studies had a heterogeneous definition of AKI as presented in Table 1. Most included studies [13–22, 24–28, 34] used standard AKI definitions [modified Risk, Injury, and Failure; and Loss; and End-stage kidney disease (RIFLE) [35], Acute Kidney Injury Network (AKIN) [36] or Kidney Disease: Improving Global Outcomes (KDIGO) criteria [37]]. AKI was diagnosed 48–72 h following/after a TAVR procedure in most included studies and only six studies [13, 15, 18, 24, 27, 28] identified AKI at 7 days following a TAVR procedure as suggested by Valve Academic Research Consortium-2 (VARC-2) consensus [38].

AKI risk

The pooled risk ratio (RR) of AKI in patients who underwent TA-TAVR was 2.26 (95% CI 1.79–2.86; $I^2 = 47\%$) (Figure 1). When meta-analysis was limited to the studies using standard AKI definitions, the pooled RR was 2.26 (95% CI 1.75–2.92; $I^2 = 53\%$). We also performed a meta-analysis of studies using VARC-2 consensus [13, 15, 18, 24, 27, 28]. The pooled RR of AKI in patients who underwent TA-TAVR was 2.19 (95% CI 1.37–3.49; $I^2 = 44\%$).

To minimize the effects of confounders, we performed a sensitivity analysis excluding the studies without adjusted analysis for known risk factors for AKI. The pooled RR of AKI remained significant in TA-TAVR [RR 2.89 (95% CI 2.12–3.94), $I^2 = 40\%$], (Figure 2).

Moderate to severe AKI risk

Data regarding severe AKI requiring renal replacement therapy (RRT) were limited; four cohort studies evaluated the risk of moderate to severe AKI in patients undergoing TA-TAVR versus TF-TAVR. The pooled RR of moderate to severe AKI in patients who underwent TA-TAVR was 1.02 (95% CI 0.57–1.80; $I^2 = 24\%$).

Table 1. Main characteristics of the studies included in this meta-analysis

	Aregger *et al.* [13]	Bagur *et al.* [23]	Elhmidi *et al.* [24]	Barbash *et al.* [34]	Kong *et al.* [16]	Nuis *et al.* [26]
Country	Switzerland	Canada	Germany	USA	Australia	Netherlands, Canada, Germany, Belgium and Columbia
Study design	Cohort study	Cohort study	Cohort study	Cohort study	Cohort study	Cohort study
Year	2009	2010	2011	2012	2012	2012
Total number	54	213	234	165	52	995
AKI definition	Serum creatinine criteria of RIFLE classification at 7 days after procedure	A decrease of >25% in eGFR at 48 h following the procedure or the need for hemodialysis during index hospitalization	Serum creatinine criteria of RIFLE classification at 7 days after procedure	Increase in SCr of ≥0.3 mg/dL or ≥50% from baseline at 72 h after procedure	Serum creatinine criteria of RIFLE classification at 48 h after procedure	Increase in SCr of ≥0.3 mg/dL or ≥50% from baseline at 72 h after procedure
RR (95% CI) for AKI	10.50 (2.22–49.69)	2.11 (0.89–5.01)	1.14 (0.53–2.47)	2.92 (1.03–8.29)	9.3 (4.3–23.7)	1.38 (0.99–1.92)
RR (95% CI) for mortality	–	In-hospital mortality 2.36 (0.91–6.12)	–	–	–	–
Confounder adjustment	None	None	None	Baseline GFR, sex, iodinated contrast per eGFR	RBC transfusion, hypertension	None
Quality assessment (Newcastle–Ottawa scale)	Selection: 3 Comparability: 0 Outcome: 3	Selection: 3 Comparability: 0 Outcome: 3	Selection: 3 Comparability: 0 Outcome: 3	Selection: 3 Comparability: 1 Outcome: 3	Selection: 3 Comparability: 1 Outcome: 3	Selection: 3 Comparability: 0 Outcome: 3

	Khawaja *et al.* [25]	Genereux *et al.* [21]	Saia *et al.* [14]	Seiffert *et al.* [17]	Tanawuttiwat *et al.* [22]	Van der boon *et al.* [20]
Country	UK	USA	Italy	Germany	USA	Italy, France, The Netherlands
Study design	Cohort study	Cohort study	Cohort study	Cohort study	Cohort study	Cohort study
Year	2012	2013	2013	2013	2014	2014
Total number	248	218	102	281	64	882
AKI definition	VARC-modified RIFLE classification stage 2 or 3 at 72 h after procedure	VARC-modified RIFLE classification stage 2 or 3 until hospital discharge	Increase in SCr of ≥0.3 mg/dL or ≥50% from baseline at 72 h after procedure	Increase in SCr of ≥0.3 mg/dL or ≥50% from baseline within 72 h after procedure	Increase in SCr of ≥0.3 mg/dL or ≥50% from baseline at 72 h after procedure	Increase in SCr of ≥0.3 mg/dL or ≥50% from baseline at 72 h after procedure
RR (95% CI) for AKI	1.71 (0.95–3.06)	2.56 (0.61–10.69)	4.57 (1.53–13.59)	1.90 (1.09–3.31) For stage 2 or 3 AKI 1.28 (0.51–3.26)	2.93 (0.96–8.96)	2.25 (1.42–3.56) For stage 3 AKI 1.92 (0.69–5.37)
RR for mortality	–	–	–	1-year mortality 1.18 (0.71–1.96)	–	In-hospital mortality 3.12 (1.43–6.82) 1-year mortality 1.88 (1.23–2.87)
Confounder adjustment	None	Age, sex, baseline creatinine, contrast volume, major vascular complication, life-threatening bleeding	Body surface area, logistic EuroScore, peripheral arterial disease, baseline GFR	None	None	Not specified

Table 1. Continued

	Khawaja *et al.* [25]	Genereux *et al.* [21]	Saia *et al.* [14]	Seiffert *et al.* [17]	Tanawuttiwat *et al.* [22]	Van der boon *et al.* [20]
Quality assessment (Newcastle–Ottawa scale)	Selection: 3 Comparability: 0 Outcome: 3	Selection: 3 Comparability: 2 Outcome: 3	Selection: 3 Comparability: 2 Outcome: 3	Selection: 3 Comparability: 0 Outcome: 3	Selection: 3 Comparability: 0 Outcome: 3	Selection: 3 Comparability: 1 Outcome: 3

	Murarka *et al.* [27]	Rouge *et al.* [28]	Van Rosendael *et al.* [15]	Thongprayoon *et al.* [18]	Schymik *et al.* [19]
Country	USA	France	The Netherlands	USA	German
Study design	Cohort study	Cohort study	Cohort study	Cohort study	Cohort study
Year	2015	2015	2015	2015	2015
Total number	123	150	210	386	708
AKI definition	Increase in SCr of ≥0.3 mg/dL or ≥50% from baseline at 7 days after procedure	Increase in SCr of ≥0.3 mg/dL or ≥50% from baseline at 7 days after procedure	Increase in SCr of ≥0.3 mg/dL or ≥50% from baseline at 7 days after procedure	An increase in SCr of ≥0.3 mg/dL within 48 h or ≥50% from the baseline at 7 days after procedure	Increase in SCr of ≥0.3 mg/dL or ≥50% from baseline at 30 days after procedure
RR (95% CI) for AKI	1.65 (0.66–4.13) For dialysis 1.16 (0.07–18.99)	1.45 (0.51–4.12)	2.76 (1.16–6.58)	2.81 (1.72–4.65)	2.09 (1.49–2.93) For stage 2 or 3 0.62 (0.33–1.19)
RR (95% CI) for mortality	30-mortality mortality 1.17 (0.23–6.03)	–	–	–	30-day mortality: 0.68 (0.38–1.21)
Confounder adjustment	None	None	Body surface area, heart rhythm, eGFR, logistic EuroScore, log-transformed calcium volume aortic valve, atherosclerosis burden	Baseline GFR, RBC transfusion, need for intra-aortic balloon pump	Propensity score matching
Quality assessment (Newcastle–Ottawa scale)	Selection: 3 Comparability: 0 Outcome: 3	Selection: 3 Comparability: 0 Outcome: 3	Selection: 3 Comparability: 2 Outcome: 3	Selection: 3 Comparability: 2 Outcome: 3	Selection: 3 Comparability: 2 Outcome: 3

AKI, acute kidney injury; BMI, body mass index; CABG, coronary bypass grafting; CKD, chronic kidney disease; CPB, cardiopulmonary bypass; DM, diabetes mellitus; GFR, glomerular filtration rate; LVEF, left ventricular ejection fraction; NR, not reported; RBC, red blood cell; RIFLE, Risk, Injury, Failure, Loss of kidney function and End-stage kidney disease; SCr, serum creatinine; TAVR, transcatheter aortic valve replacement.

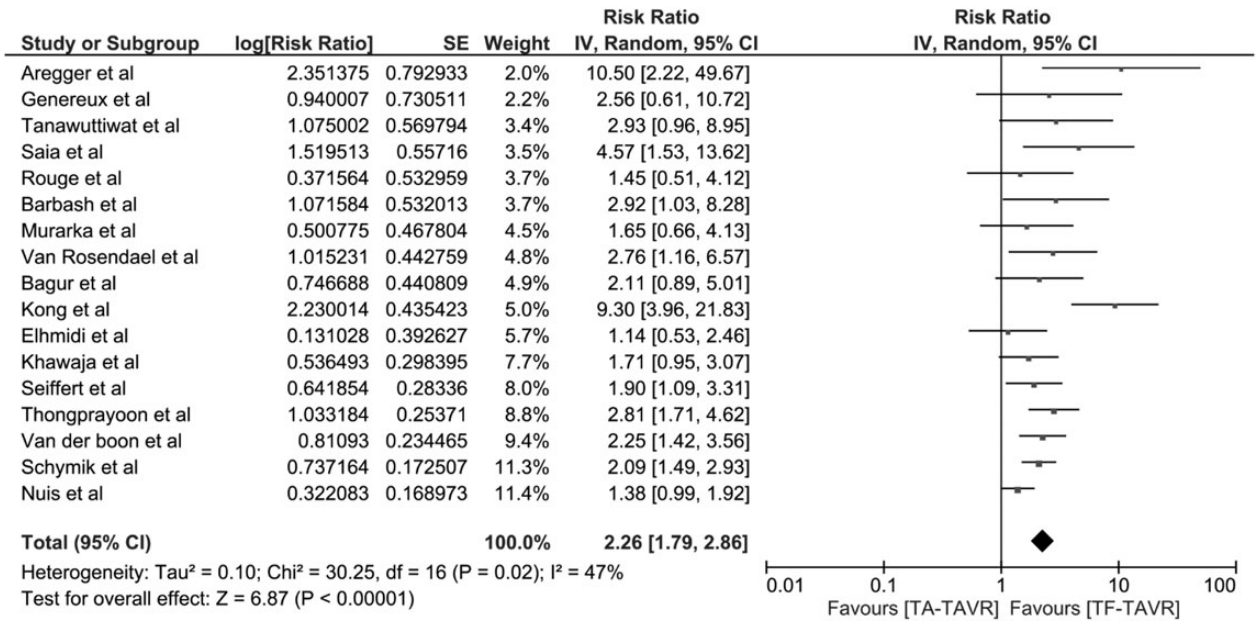

Fig. 1. Forest plot of the included studies comparing AKI risk in patients who underwent TA-TAVR and those with TF-TAVR. Square data markers express RRs; horizontal lines are the 95% CIs with marker size indicating the statistical weight of the study using random effects meta-analysis. A diamond data marker denotes the overall RR and 95% CI for the outcome of interest.

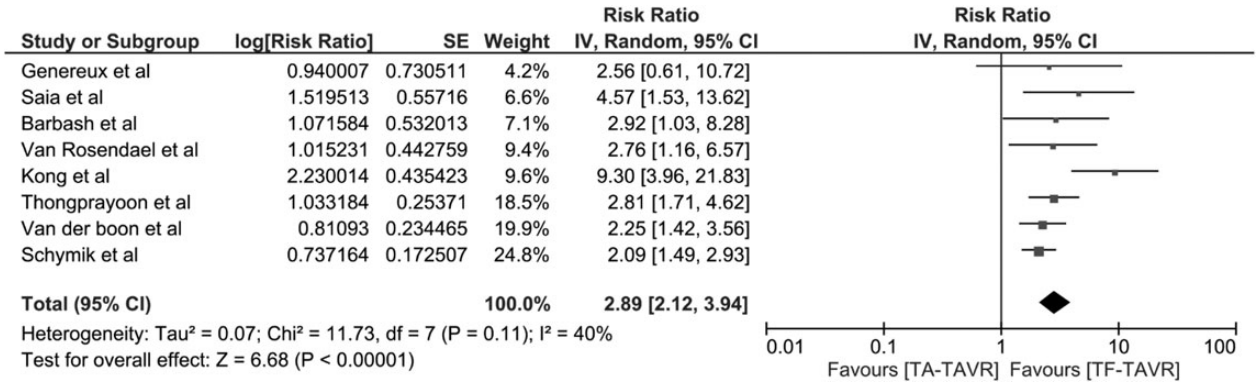

Fig. 2. Forest plot of the included studies with adjusted analysis comparing AKI risk in patients who underwent TA-TAVR and those with TF-TAVR. Square data markers express RRs; horizontal lines are the 95% CIs with marker size indicating the statistical weight of the study using random effects meta-analysis. A diamond data marker denotes the overall RR and 95% CI for the outcome of interest.

Evaluation for publication bias

Funnel plots to evaluate publication bias for the risk of AKI in patients undergoing TA-TAVR versus TF-TAVR are summarized in Supplementary data, Figures S1 and S2. These graphs demonstrate no obvious asymmetry and thus suggest an insignificant publication bias.

Discussions

In this systematic review, we demonstrated a significant association between TA-TAVR and an overall 2.4-fold increased risk of AKI compared with those who underwent TF-TAVR. We were not able to show a significant difference in the incidence of moderate to severe AKI requiring RRT between patients in the two cohorts.

Although the mechanisms behind the higher frequency of AKI in TA-TAVR when compared with TF-TAVR are only speculative, there are several plausible explanations [6]. First, TF-TAVR has the advantage of implementation with local anesthesia and monitored anesthesia care rather than full general anesthesia. Second, procedure times for TF-TAVR are generally shorter [8, 10–12]. Both of these factors limit exposure to general anesthesia that may cause significant hemodynamic perturbations affecting renal perfusion and thereby cause a higher rate of AKI [12]. This potential risk confirms that TA-TAVR must be performed under general anesthesia. Third, there is a difference in the demographics of patient populations undergoing TA-TAVR and TF-TAVR. Patients who undergo TA-TAVR have more advanced atherosclerotic disease, which is a risk factor for AKI after TAVR [6, 13]. In our analysis of these studies, we adjusted for potential confounders and yet still demonstrated a significantly increased risk for AKI in patients who undergo TA-TAVR.

Despite a higher incidence of AKI in patients treated with TA-TAVR, our meta-analysis demonstrated that the risk of

moderate to severe AKI was not significantly different. The data to analyze these particular outcomes, however, are limited, and additional studies will be required to delineate the relationship between TAVR approaches and AKI. Lastly, additional analyses are needed to ascertain whether this ultimately translates into a higher rate of RRT and mortality.

Although the selected studies were all of moderate to high quality, there are some limitations to the results. First, there are statistical heterogeneities in the final analysis. The potential sources of these heterogeneities include variations in the diagnosis methodology of AKI following TAVR and the differences in confounder adjusted methods. Second, as mentioned previously, data on severe AKI and subsequent mortality after TA-TAVR versus TF-TAVR are lacking. Therefore, we need studies on a larger scale to focus on the important outcomes, including the development of chronic kidney disease, the need for long-term dialysis and short and long-term mortality. Finally, this is a meta-analysis of observational studies with the inherent limitation of being able to confirm an association but not a causal relationship.

In summary, our meta-analysis demonstrates an association between TA-TAVR and a higher risk of AKI when compared with TF-TAVR. However, the risk of moderate to severe AKI following TA-TAVR and TF-TAVR is not significantly different.

Supplementary data

Supplementary data are available online at http://ndt.oxfordjournals.org.

Author contributions

All investigators had access to the data and played essential roles in writing the manuscript.

Conflict of interest statement

None declared.

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