Incidence of Renal Failure Requiring Hemodialysis Following Transcatheter Aortic Valve Replacement

Vatsal Ladia, MD, Hemang B. Panchal, MD, MPH, Terrence J. O'Neil, MD, Puja Sitwala, MD, Samit Bhatheja, MD, MPH, Rakeshkumar Patel, MD, Vijay Ramu, MD, Debabrata Mukherjee, MD, Ehtisham Mahmud, MD and Timir K. Paul, MD, PhD

ABSTRACT

Objective: Studies have shown that iodinated radiocontrast use is associated with acute renal failure especially in the presence of chronic kidney disease and multiple factors modulate this risk. The purpose of this meta-analysis is to compare the incidence of renal failure requiring hemodialysis between transfemoral (TF) and transapical (TA) transcatheter aortic valve replacement using the Edwards valve.

Methods: The PubMed database was searched from January 2000 through December 2014. A total of 10 studies ($n = 2,459$) comparing TF ($n = 1,268$) and TA ($n = 1,191$) TAVR procedures using the Edwards valve were included. Variables of interest were baseline logistic EuroSCORE, prevalence of diabetes mellitus, hypertension, peripheral arterial disease, chronic kidney disease and amount of contrast used. The primary endpoint was incidence of renal failure requiring hemodialysis. The odds ratio and 95% CI were computed and $P < 0.05$ was considered as the level of significance.

Results: The logistic EuroSCORE was significantly higher in TA compared to TF ($P = 0.001$) TAVR. The amount of contrast (mL) used was significantly higher in the TF group compared to the TA group (mean difference: 36.9, CI: 25.7-48.1, $P < 0.001$). The incidence of hemodialysis following the procedure was significantly higher in the TA group compared to TF group (odds ratio = 4.3, CI: 2.4-7.8, $P < 0.00001$).

Conclusions: This meta-analysis suggests that despite the lower amount of contrast used in TA-TAVR, the incidence of renal failure requiring hemodialysis was higher with the Edwards valve. This suggests that the incidence of renal failure requiring hemodialysis after TAVR is associated with baseline comorbidities in the TA-TAVR group rather than the volume of contrast used.

Key Indexing Terms: Transcatheter aortic valve replacement; Transfemoral; Transapical; Renal failure; Hemodialysis. **[Am J Med Sci 2016;352(3):306–313.]**

INTRODUCTION

Transcatheter aortic valve replacement (TAVR) is an alternative and equally safe approach to surgical aortic valve replacement for patients with severe aortic stenosis who are not surgical candidates.[1] TAVR is performed using transfemoral, transapical, subclavian and transaortic approaches. Transfemoral TAVR (TF-TAVR) is a retrograde approach, whereas transapical TAVR (TA-TAVR) is an antegrade approach with apical minithoracotomy. TF-TAVR is preferred due to being less invasive, having lower periprocedural complications and being technically less demanding.[2] Studies have demonstrated that there is no difference in long-term mortality and major adverse cardiovascular and cerebrovascular events following TAVR procedures with transfemoral or transapical approaches.[3,4] Renal impairment following TAVR is the third most common adverse event and occurs in as many as 41% of patients after the procedure, and those who require hemodialysis have 50% in-hospital mortality.[5-9] The objective of this meta-analysis is to compare postprocedural incidence of acute renal failure (ARF) requiring hemodialysis between TF-TAVR and TA-TAVR using the Edwards valves.

METHODS

This meta-analysis was performed in accordance with Meta-analysis of Observational Studies in Epidemiology statements for reporting systematic reviews.[10] General guidelines of Cochrane Handbook for Systematic Reviews of Interventions, Version 5.0.2, were used in developing methodology, and meta-analysis was conducted in adherence to these guidelines.[10] We searched the National Library of Medicine PubMed, National Institute of Health clinical trials registry and the Cochrane Central Register of Controlled Trials to include clinical studies comparing the incidence of postprocedural renal failure requiring hemodialysis between TF-TAVR and TA-TAVR performed using Edwards valves on patients with severe aortic stenosis. Studies were included if conducted during the period of January 2000 through December 2014. The keywords used for searching studies were "transcatheter,"

"aortic valve," "aortic stenosis," "aortic valve replacement," "TAVI," "transfemoral," "transapical," "TAVR," "hemodialysis" and "renal failure." In addition to our computerized search, we manually reviewed the reference lists and related links of all retrieved articles to complete our search. Further, 2 independent authors (H.B.P. and V.M.L.) reviewed all titles from the search results, and articles were selected for final data extraction. Figure 1 outlines the selection process.

Studies comparing outcomes between TF-TAVR and TA-TAVR procedures using Edwards valves were included in this meta-analysis. To be selected for analysis, a study had to meet the following inclusion criteria: (1) study demonstrates complications or outcomes of TF-TAVR and TA-TAVR performed using Edwards valves in patients with severe aortic stenosis, and (2) study reports postprocedural renal failure events requiring hemodialysis. Included studies did not provide exact timing of postprocedural incidence of renal failure; however, all studies consistently reported the incidence of renal failure as in-hospital and 30-day outcome. Only 2 studies specifically defined renal failure as 75% reduction in glomerular filtration rate or urine output < 0.5 mL/h/kg or anuria for 12 hours according to RIFLE criteria,[11] serum creatinine levels > 200 μmol/L or anuria and 3 times increase in serum creatinine.[12]

After identifying all relevant articles, we extracted data from each study including authors, year, design, sample size, types of TAVR procedure, baseline clinical characteristics of patient population (hypertension, diabetes mellitus, chronic kidney disease [CKD], peripheral vascular disease), baseline logistic EuroSCORE or STS score representing perioperative risk and postprocedural outcomes. The objective of this study was to compare the incidence of renal failure requiring hemodialysis following TAVR using Edwards valve for severe aortic stenosis. Further, 2 reviewers (H.B.P. and V.M.L.) independently extracted data and assessed outcomes. The interrater agreement was 90%, and disagreements were resolved by consensus.

The quality of the included studies in present analysis was assessed using the Newcastle-Ottawa (http://www.ohri.ca/programs/clinical_epidemiology/oxford.htm) quality assessment scale for cohort studies. Briefly, studies were quoted using prespecified items on patients' selection (representativeness and selection of patients, ascertainment of exposure), comparability of cohorts and assessment of outcomes (recording, adequacy of follow-up). Ratings for each item were added to provide a study quality score (maximal score, 9). A total of 2 independent reviewers performed the Newcastle-Ottawa Scale grading. Discrepancies were solved on consensus basis.

The mean difference (MD) or odds ratio across all studies with corresponding 95% CI was calculated for each endpoint by using RevMan 5.3 statistical software

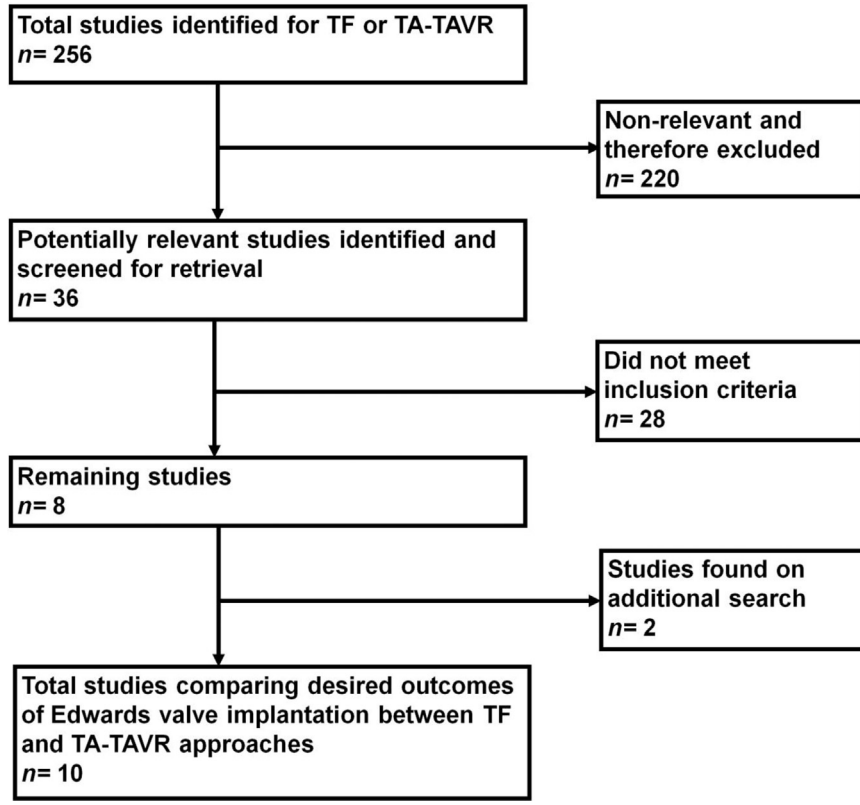

FIGURE 1. Study selection process.