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Association between transcatheter aortic valve implantation or replacement and mortality, and major adverse events after coronary artery bypass grafting

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ABSTRACT

Background: In recent years, many people are opting for minimally invasive surgery in China. Patients undergoing transcatheter aortic valve implantation or replacement (TAVIR) with previous coronary artery bypass grafting (CABG) have higher risks of death and major complications.

Materials/methods: PubMed and Embase were searched for all comparison studies between TAVIR with and without prior CABG and mortality as a primary outcome, irrespective of surgical risk, to investigate whether patients with prior CABG can undergo TAVIR. Randomized controlled trials and propensity-score-matched cohort studies were eligible for inclusion. The outcomes of interest included 30-day, 6-month, and 1-year mortality and 30-day complications. If significant heterogeneity was found in the random-effects meta-analyses, a sensitivity analysis that individually removed each study was conducted.

Results: Five studies reported results on patients undergoing TAVIR with or without prior CABG. Compared with the non-CABG cohort, the CABG cohort showed no significant difference in the 30-day, 6-month, and 1-year mortality and the 30-day risk of major complications, except life-threatening bleeding. However, for the 30-day risk of life-threatening bleeding, the morbidity of CABG cohort was significantly lower than that of the non-CABG cohort (risk ratio 0.555; 95% confidence interval 0.35–0.85; $P = 0.006$; $I^2 = 0\%$).

Conclusions: Patients with prior CABG can undergo TAVIR. Patients undergoing TAVIR without prior CABG need more attention because of a higher risk of life-threatening bleeding.

1. Introduction

Aortic stenosis (AS) is one of the most common valvular heart diseases in elderly individuals. It always occurs in conjunction with coronary artery disease (CAD) because of the similarities in risk factors and pathogenesis. Severe symptomatic AS carries a poor prognosis. Aortic valve replacement (AVR) is established as a Class I indication for patients with severe AS who are symptomatic or those with impairment of left ventricular function in the absence of symptoms [1]. Until recently, surgical aortic valve replacement was the standard of care in adults with severe symptomatic AS. However, the risks associated with surgical aortic valve replacement (SAVR) increase in elderly patients, those with concomitant severe systolic heart failure or CAD, and those with comorbidities such as cerebrovascular disease, peripheral arterial disease, arrhythmia, chronic kidney disease, chronic respiratory dysfunction, bacterial translocation, and systematic inflammation response syndrome [2–4]. In addition, the mortality rate is higher in high-risk patients undergoing combined SAVR and coronary artery bypass grafting (CABG) than in those undergoing isolated SAVR [5].

In recent years, many people are opting for minimally invasive surgery in China. In addition, the mortality and morbidity rates are much lower than earlier since the introduction of transcatheter aortic valve implantation or replacement (TAVIR) [6]. A systematic review and meta-analysis comparing the effects of transfemoral (TF)-TAVR and SAVR on clinical outcomes, regardless of patient risk, provides more information on the effect of the access route on patient complications [7]. Similarly, the mortality rate is also significantly lower in patients undergoing TAVIR than in those undergoing standard therapy, who cannot

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undergo surgery [8]. Still, many patients die after undergoing TAVIR because of their condition before and after the surgery [9–11].

A surgical history of CAD is one of the most common risk factors for patients undergoing valve implantation or replacement [12–14], especially for patients with prior CABG. Patients with prior CABG undergoing TAVIR have higher risks of death and major complications. However, no definitive conclusions have been drawn from the available data about whether patients with prior CABG should undergo TAVIR and have a similar incidence of complications. This study was performed to evaluate the clinical outcomes of patients with prior CABG undergoing TAVIR. Also, it aimed to show which parts must be checked up more frequently.

2. Materials and methods

A systematic review of the clinical outcomes was performed on patients with or without prior CABG undergoing TAVIR according to the guidelines from the PubMed of Systematic Reviews and the recommendations of Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA). A computerized search was carried out by two reviewers to identify all relevant studies published in PubMed and Embase databases up to the end of January 10, 2018.

The following search terms were used: TAVI OR TAVR OR "transcatheter aortic valve" AND "Coronary artery bypass." Languages were no limitation, and species were limited to humans only. Citations were screened at the title and abstract levels and retrieved as a full text if they reported the outcome of TAVIR with prior CABG. References of the acquired studies were also searched manually to identify any further relevant studies for the inclusion.

All studies fulfilling the following criteria were included: (1) enrollment for TAVIR based on existing and accepted guidelines; (2) enrolled consecutive patients; (3) adverse events including mortality in patients with prior CABG undergoing TAVIR and other complications; and (4) a follow-up period no less than 30 days. Studies were excluded if any of the following criteria applied: (1) duplicate publication or overlap of patients; (2) abstracts, case reports, review, letter or correspondence, conference presentations, and editorials; (3) mortality of patients undergoing TAVIR not clearly reported or impossible to extract from the published results; and (4) the number of patients with prior CABG less than one fifth of the total population.

Two investigators verified the abstracts and full-text studies independently. The following information was collected: first author, year of publication, region, study design, valve type, inclusion period, sample size, follow-up period, and population baseline characteristics. Cochrane collaboration's tool for assessing the risk of bias was applied for randomized controlled trials or clinical trials and Newcastle–Ottawa Scale 11 was applied for observational studies to assess the methodological quality of studies. Discriminations were resolved by consensus with a third investigator.

The primary endpoint was early and mid-term mortality, including three time points: 30-day, 6-month, and 1-year. The secondary endpoint was 30-day complications from any causes during the follow-up period. If the forest map showed some reports having more weightage than others, it was plotted again after removing these reports to find whether they influenced the overall results.

The data were analyzed using Stata software version 14.0. The risk ratio (RR) with the corresponding 95% confidence interval (CI) was calculated for each endpoint across all studies. A two-sided error of less than 0.05 was considered statistically significant. Heterogeneity of the studies was assessed using Thompson's I^2 test. Significant heterogeneity was present if I^2 was more than 50%. For all the studies with or without I^2 more than 50%, the random-effects model was used for analysis. The origin of heterogeneity was calculated using the meta-regression and subgroup analyses. Sensitivity analysis was performed by deleting one study at a time, and a more than 20% modification of the overall effect was considered significant if a given study was excluded. Publication bias was evaluated using a funnel plot.

3. Results

3.1. Selected studies

Overall, 425 abstracts were identified using the search criteria, and 392 studies underwent a full review (Fig. 1). Of the studies fully reviewed, 377 were excluded: 165 for no propensity matching, 86 for no control arm, 69 case reports, 38 review articles, 14 only abstracts, 3 method papers, and 2 meta-analyses. A total of 15 studies met the final inclusion criteria, of which 6 reported unmatched data and 4 reported duplicate results. The baseline characteristics of the TAVIR studies and patients are reported in Table 1 and Supplementary Table 1, respectively. The data on STS-PROM or EuroScore were also reported in Table S1. In addition, the procedural characteristics of patients are reported in Supplementary Table 2.

3.1.1. Mortality

Four studies, including 4837 patients, reported 30-day mortality. No significant difference was observed in the 30-day mortality (RR 0.943; 95% CI 0.75–1.19; $P = 0.617$; $I^2 = 0\%$) in patients who underwent TAVIR with prior CABG compared with patients without prior CABG (Fig. 2A). Three studies (4.390 patients) reported 6-month mortality. Patients undergoing CABG had the same 6-month risk of mortality as those not undergoing CABG (RR 0.962; 95% CI 0.80–1.15; $P = 0.671$; $I^2 = 0\%$) (Fig. 2B). All five studies, including 4963 patients, showed 1-year mortality. No significant difference was noted in the 1-year mortality (RR 0.942; 95% CI 0.81–1.09; $P = 0.420$; $I^2 = 0\%$) in patients undergoing CABG compared with those without CABG (Fig. 2C). Funnel plots did not indicate publication bias in any of the outcomes (Supporting Information, Fig. S2A–C).

Similarly, the effect on the 30-day, 6-month, and 1-year mortality after removing the study of maximum weightage alone did not show any significant difference between the two groups either (RR 0.902; 95% CI 0.54–1.52; $P = 0.700$; RR 1.030; 95% CI 0.47–2.27; $P = 0.941$; and RR 0.941; 95% CI 0.71–1.25; $P = 0.677$, respectively) (Supporting Information, Fig. S3A–C).

3.1.2. Implantation success

Three studies (4334 patients) reported the cases of implantation success. The risk of implantation success in the CABG cohort was not significantly different compared with that in the non-CABG cohort (RR 0.997; 95% CI 0.98–1.01; $P = 0.595$; $I^2 = 0\%$) (Fig. 2D). Funnel plots did not indicate publication bias in any of the outcomes (Supporting Information, Fig. S2D).

3.1.3. New-onset atrial fibrillation

Two studies (498 patients) reported the 30-day incidence of new atrial fibrillation. The risk of new atrial fibrillation in the CABG cohort was not significantly different compared with that in the non-CABG cohort (RR 0.658; 95% CI 0.23–1.86; $P = 0.430$; $I^2 = 76.8\%$) (Supporting Information, Fig. S1A). Publication bias could not be assessed given the limited number of studies evaluating the new-onset atrial fibrillation.

3.1.4. Acute kidney injury

Two studies (498 patients) reported the 30-day incidence of acute kidney injury. Patients with prior CABG had no significant difference in the 30-day risk of acute kidney injury compared with patients without prior CABG (RR 1.001; 95% CI 0.65–1.54; $P = 0.997$; $I^2 = 0\%$) (Supporting Information, Fig. S1B). Publication bias could not be assessed given the limited number of studies evaluating acute kidney injury.